DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 495

[CMS–1716–P]

RIN 0938–AT73

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2020 and to implement certain recent legislation. We also are proposing to make changes relating to Medicare graduate medical education (GME) for teaching hospitals and payments to critical access hospital (CAHs). In addition, we are proposing to provide the market basket update that would apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis, subject to these limits for FY 2020. We are proposing to update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2020. In this proposed rule, we are including proposals to address wage index disparities between high and low wage index hospitals; to provide for an alternative IPPS new technology add-on payment pathway for certain transformative new devices; and to revise the calculation of the IPPS new technology add-on payment. In addition, we are requesting public comments on the substantial clinical improvement criterion used for evaluating applications for both the IPPS new technology add-on payment and the OPPS transitional pass-through payment for devices, and we discuss potential revisions that we are considering adopting as final policies related to the substantial clinical improvement criterion for applications received beginning in FY 2020 for IPPS (that is, for FY 2021 and later new technology add-on payments) and beginning in CY 2020 for the OPPS.

We are proposing to establish new requirements or revise existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs). We also are proposing to establish new requirements and revise existing requirements for eligible hospitals and critical access hospitals (CAHs) participating in the Medicare and Medicaid Promoting Interoperability Programs. We are proposing to update policies for the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on June 24, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1716–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1716–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1716–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Donald Thompson, (410) 786–4487, and Michele Hudson, (410) 786–4487, Operating Prospective Payment, MS–DRGs, Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Medicare-Dependent Small Rural Hospital (MDH) Program, Low-Volume Hospital Payment Adjustment, and Critical Access Hospital (CAH) Issues.

Michele Hudson, (410) 786–4487, Mark Luxton, (410) 786–4530, and Emily Lipkin, (410) 786–3633, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, (410) 786–0110, Frontier Community Health Integration Project Demonstration Issues.

Erin Patton, (410) 786–2437, Hospital Readmissions Reduction Program Administration Issues.

Lein Han, 410–786–0205, Hospital Readmissions Reduction Program—Readmissions—Measures Issues.

Michael Brea, (410) 786–4961, Hospital-Acquired Condition Reduction Program Issues.

Annese Abdullah-Mclaughlin, (410) 786–2995, Hospital-Acquired Condition Reduction Program—Measures Issues.

Grace Snyder, (410) 786–0700 and James Poyer, (410) 786–2261, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Program Administration, Validation, and Reconsideration Issues.

Cindy Tourison, (410) 786–1093, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Nekeshia McInnis, (410) 786–4486 and Ronique Evans, (410) 786–1000, PPS-Exempt Cancer Hospital Quality Reporting Issues.

Mary Pratt, (410) 786–6867, Long-Term Care Hospital Quality Data Reporting Issues.

Elizabeth Holland, (410) 786–1309, Dylan Podson (410) 786–5031, and Bryan Rossi (410) 786–065l, Promoting Interoperability Programs.

Benjamin Moll, (410) 786–4390, Provider Reimbursement Review Board Appeals Issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov/*. Follow the search instructions on that website to view public comments.

Electronic Access

This **Federal Register** document is available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the internet at: *http://www.gpo.gov/fdsys*.

Tables Available Through the Internet on the CMS Website

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to the proposed rule and the final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, the majority of the IPPS tables and LTCH PPS tables are no longer published in the **Federal Register**. Instead, these tables, generally, will be available only through the internet. The IPPS tables for this FY 2020 proposed rule are available through the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2020 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2020 proposed rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1716–P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified above should contact Michael Treitel at (410) 786–4552.

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I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This proposed rule also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. In this proposed rule, we are including proposals to address wage index disparities between high and low wage index hospitals; to provide for an alternative IPPS new technology add-on payment pathway for certain transformative new devices; and to revise the calculation of the IPPS new technology add-on payment. In addition, we are requesting public comments on the substantial clinical improvement criterion for evaluating applications for both the IPPS new technology add-on payment and the OPPS transitional pass-through payment for devices, and we discuss potential revisions that we are considering adopting as final policies related to the substantial clinical improvement criterion for FY 2020 for IPPS and CY 2020 for the OPPS.

We are proposing to establish new requirements and revise existing requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs) that are participating in Medicare. We also are proposing to establish new requirements and revise existing requirements for eligible hospitals and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs. We are proposing to update policies for the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

Under various statutory authorities, we are proposing to make changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2020 and subsequent fiscal years. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the BBRA (Pub. L. 106–113) and section 307(b)(1) of the BIPA (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.

• Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.

• Section 1866(k) of the Act, which establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''

• Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.

• Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.

• Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.

• Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.

• Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions.

• Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.

• Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016, and provides for a 4-year transitional blended payment rate for discharges occurring in LTCH cost reporting periods beginning in FYs 2016 through 2019. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026.

• Section 1886(m)(5)(D)(iv) of the Act, as added by section 1206(c) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which provides for the establishment of a functional status quality measure in the LTCH QRP for change in mobility among inpatients requiring ventilator support.

• Section 1899B of the Act, as added by section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.

2. Summary of the Major Provisions

Below we provide a summary of the major provisions in this proposed rule. In general, these major provisions are being proposed as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the proposed changes in this proposed rule is presented in section I.D. of the preamble of this proposed rule.

a. Proposed MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. The FY 2014 through FY 2017 adjustments represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110 90. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.) Therefore, for FY 2020, we are proposing to make an adjustment of + 0.5 percent to the standardized amount.

b. Request for Information on the New Technology Add-On Payment and Transitional Device Pass-Through Payment Substantial Clinical Improvement Criterion and Discussion of Potential Revisions to the New Technology Add-On Payment and Transitional Device Pass-Through Payment Substantial Clinical Improvement Criterion

The substantial clinical improvement criterion that is used to evaluate a technology that is the subject of an application for the new technology add-on payment under the IPPS or an application for the transitional pass-through payment for additional costs of innovative devices under the OPPS is the subject of the request for information and the discussion of potential revisions included in this proposed rule.

We understand that greater clarity regarding what would substantiate the requirements of this criterion would help the public, including innovators, better understand how CMS evaluates new technology applications for add-on payments and provide greater predictability about which applications will meet the criterion for substantial clinical improvement. We are considering potential revisions to the substantial clinical improvement criterion under the IPPS new technology add-on payment policy and the OPPS transitional pass-through payment policy for devices policy, and are seeking public comments on the type of additional detail and guidance that the public and applicants for new technology add-on payments would find useful. The comments we receive in response to those general questions will inform future rulemaking after the FY 2020 IPPS/LTCH PPS final rule. This request for public comments is intended to be broad in scope and provide a foundation for potential rulemaking in future years.

In addition to this broad request for public comments for potential rulemaking in future years, in order to respond to stakeholder feedback requesting greater understanding of CMS' approach to evaluating substantial clinical improvement, we are soliciting public comments on specific changes or clarifications to the IPPS and OPPS substantial clinical improvement criterion that CMS might consider making in the FY 2020 IPPS/LTCH PPS final rule for applications received beginning in FY 2020 for the IPPS and CY 2020 for the OPPS to provide greater clarity and predictability.

c. Proposed Alternative Inpatient New Technology Add-On Payment Pathway for Transformative New Devices

After consideration of the issues discussed in section III.H.8. of the preamble of this proposed rule relating to the Food and Drug Administration's (FDA's) expedited programs, and consistent with the Administration's commitment to addressing barriers to health care innovation and ensuring that Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes, we concluded that it would be appropriate to develop an alternative pathway for the inpatient new technology add-on payment for transformative medical devices. In situations where a new medical device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization (that is, the device has received pre-market approval (PMA); 510(k) clearance; or the granting of a De Novo classification request), we are proposing an alternative inpatient new technology add-on payment pathway to facilitate access to this technology for Medicare beneficiaries.

Specifically, we are proposing that, for applications received for IPPS new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of the FDA's Breakthrough Devices Program and received FDA marketing authorization, such a device would be considered new and not substantially similar to an existing technology for purposes of new technology add-on payment under the IPPS. In light of the criteria applied under the FDA's Breakthrough Devices Program, and because the technology may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization, we also are proposing that the medical device would not need to meet the requirement under 42 CFR 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

d. Proposed Revision of the Calculation of the Inpatient Hospital New Technology Add-On Payment

The current calculation of the new technology add-on payment is based on the cost to hospitals for the new medical service or technology. Under § 412.88, if the costs of the discharge (determined by applying cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology or medical service.

After consideration of the concerns raised by commenters and other stakeholders, we agree that there may be merit to the recommendations to increase the maximum add-on amount, and that capping the add-on payment amount at 50 percent could, in some cases, no longer provide a sufficient incentive for the use of new technology. To address this issue, we believe it would be appropriate to modify the current payment mechanism to increase the amount of the maximum add-on payment amount to 65 percent. Therefore, we are proposing that, beginning with discharges occurring on or after October 1, 2019, if the costs of a discharge involving a new medical service or technology exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare would make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

e. Proposals To Address Wage Index Disparities Between High and Low Wage Index Hospitals

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20372), we invited the public to submit further comments, suggestions, and recommendations for regulatory and policy changes to the Medicare wage index. Many of the responses received from this request for information (RFI) reflect a common concern that the current wage index system perpetuates and exacerbates the disparities between high and low wage index hospitals. Many respondents also expressed concern that the calculation of the rural floor has allowed a limited number of States to manipulate the wage index system to achieve higher wages for many urban hospitals in those States at the expense of hospitals in other States, which also contributes to wage index disparities.

To help mitigate these wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications under 42 CFR 412.103 in the rural floor, we are proposing to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and decreasing the wage index values for certain hospitals with high wage index values for budget neutrality purposes, as well as changing the calculation of the rural floor. We also are proposing a transition for hospitals experiencing significant decreases in their wage index values as a result of these proposed changes. We are proposing to make these changes in a budget neutral manner.

In this proposed rule, we are proposing to increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. Furthermore, we are

proposing that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. Under our proposal, in order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, we are proposing to decrease the wage index values for certain hospitals with high wage index values (that is, hospitals with wage index values above the 75th percentile wage index value), but preserve the rank order among those values.

In addition, we are proposing to remove urban to rural reclassifications from the calculation of the rural floor, such that, beginning in FY 2020, the rural floor would be calculated without including the wage data of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103). Also, for the purposes of applying the provisions of section 1886(d)(8)(C)(iii) of the Act, we are proposing to remove urban to rural reclassifications from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in the statute.

Lastly, for FY 2020, we are proposing to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019. We are proposing to apply a budget neutrality adjustment to the standardized amount so that our proposed transition for hospitals that could be negatively impacted is implemented in a budget neutral manner.

f. Proposed DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY 2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, DSHs receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to update our estimates of the three factors used to determine uncompensated care payments for FY 2020. We are proposing to continue to use uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) in the calculation of Factor 2. We also are proposing to use a single year of data on uncompensated care costs from Worksheet S–10 for FY 2015 to determine Factor 3 for FY 2020. We also are seeking public comments on whether we should, due to changes in the reporting instructions that became effective for FY 2017, alternatively use a single year of Worksheet S–10 data from the FY 2017 cost reports, instead of the FY 2015 Worksheet S–10 data, to calculate Factor 3 for FY 2020. In addition, we are proposing to continue to use only data regarding low-income insured days for FY 2013 to determine the amount of uncompensated care payments for Puerto Rico hospitals, and Indian Health Service and Tribal hospitals. We are not proposing specific Factor 3 polices for all-inclusive rate providers for FY 2020. In this proposed rule, we also are proposing to continue to use the following established policies: (1) For providers with multiple cost reports, beginning in the same fiscal year, to use the longest cost report and annualize Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (2) in the rare case where a provider has multiple cost reports beginning in the same fiscal year, but one report also spans the entirety of the following fiscal year, such that the hospital has no cost report for that fiscal year, to use the cost report that spans both fiscal years for the latter fiscal year; and (3) to apply statistical trim methodologies to potentially aberrant cost-to-charge ratios (CCRs) and potentially aberrant uncompensated care costs reported on the Worksheet S–10.

g. Proposed Changes to the LTCH PPS

In this proposed rule, we set forth proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2020. We also are proposing the payment adjustment for LTCH discharges when the LTCH does not meet the applicable discharge payment percentage and a proposed reinstatement process, as required by section 1886(m)(6)(C) of the Act. An LTCH would be subject to this payment adjustment if, for cost reporting periods beginning in FY 2020 and subsequent fiscal years, the LTCH's percentage of Medicare discharges that meet the criteria for exclusion from the site neutral payment rate (that is, discharges paid the LTCH PPS standard Federal payment rate) of its total number of Medicare FFS discharges paid under the LTCH PPS during the cost reporting period is not at least 50 percent.

h. Reduction of Hospital Payments for Excess Readmissions

We are proposing to make changes to policies for the Hospital Readmissions Reduction Program, which was established under section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2017 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. In this proposed rule, we are proposing the following policies: (1) A measure removal policy that aligns with the removal factor policies previously adopted in other quality reporting and quality payment programs; (2) an update to the Program's definition of ''dual-eligible'' beginning with the FY 2021 program year to allow for a 1-month lookback period in data sourced from the State Medicare Modernization Act (MMA) files to determine dual-eligible status for beneficiaries who die in the month of discharge; (3) a subregulatory process to address any potential future nonsubstantive changes to the payment adjustment factor components; and (4) an update to the Program's regulations at 42 CFR 412.152 and 412.154 to reflect proposed policies and to codify additional previously finalized policies.

i. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this proposed rule, we are proposing that the Hospital VBP

Program will use the same data used by the HAC Reduction Program for purposes of calculating the Centers for Disease Control and Prevention (CDC) National Health Safety Network (NHSN) Healthcare-Associated Infection (HAI) measures beginning with CY 2020 data collection, when the Hospital IQR Program will no longer collect data on those measures, and will rely on HAC Reduction Program validation to ensure the accuracy of CDC NHSN HAI measure data used in the Hospital VBP Program. We also are newly establishing certain performance standards.

j. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act establishes an incentive to hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to make an adjustment to payments to applicable hospitals effective for discharges beginning on October 1, 2014. This 1-percent payment reduction applies to hospitals that rank in the worst-performing quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. As part of our agency-wide Patients over Paperwork and Meaningful Measures Initiatives, discussed in section I.A.2. of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 and 41148), we are proposing to: (1) Adopt a measure removal policy that aligns with the removal factor policies previously adopted in other quality reporting and quality payment programs; (2) clarify administrative policies for validation of the CDC NHSN HAI measures; (3) adopt the data collection periods for the FY 2022 program year; and (4) update 42 CFR 412.172(f) to reflect policies finalized in the FY 2019 IPPS/LTCH PPS final rule.

k. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase that would otherwise apply to the standardized amount applicable to discharges occurring in that fiscal year.

In this proposed rule, we are proposing to make several changes. We are proposing to: (1) Adopt two opioid-related eCQMs (Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) and Hospital Harm—Opioid-Related Adverse Events eCQM) beginning with the CY 2021 reporting period/FY 2023 payment determination; (2) adopt the Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) measure (NQF #2879) in a stepwise fashion, beginning with two voluntary reporting periods which would run from July 1, 2021 through June 30, 2022, and from July 1, 2022 through June 30, 2023, before requiring reporting of the measure for the reporting period that would run from July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination and for subsequent years; and (3) remove the Claims-Based Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789) (HWR claims-only measure) beginning with the FY 2026 payment determination. We also are proposing reporting and submission requirements for eCQMs, including proposals to: (1) Extend current eCQM reporting and submission requirements for both the CY 2020 reporting period/FY 2022 payment determination and CY 2021 reporting period/FY 2023 payment determination; (2) change eCQM reporting and submission requirements for the CY 2022 reporting period/FY 2024 payment determination, such that hospitals would be required to report one, self-selected calendar quarter of data for three self-selected eCQMs and the proposed Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e), for a total of four eCQMs; and (3) continue requiring that EHRs be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. These proposals are in alignment with proposals under the Promoting Interoperability Program. We also are proposing reporting and submission requirements for the Hybrid HWR measure. In addition, we are seeking public comments on three measures for potential future inclusion in the Hospital IQR Program.

l. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

The LTCH QRP is authorized by section 1886(m)(5) of the Act and applies to all hospitals certified by Medicare as long-term care hospitals (LTCHs). Under the LTCH QRP, the Secretary must reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH fails to submit data in accordance with the LTCH QRP requirements specified for that fiscal year. As discussed in section VIII.C. of the preamble of this proposed rule, we are proposing to adopt two measures that meet the requirements of section 1899B(c)(1)(E) of the Act, modify an existing measure, and adopt new standardized patient assessment data elements that satisfy section 1899B(b) of the Act. We also are proposing to move the implementation date of the LTCH Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set or LCDS) from April to October to align with other post-acute care programs beginning October 1, 2020. Lastly, we are proposing updates related to the system used for the submission of data and related regulations.

m. Medicare and Medicaid Promoting Interoperability Programs

For purposes of an increased level of stability, reducing the burden on eligible hospitals and CAHs, and clarifying certain existing policies, we are proposing several changes to the Medicare Promoting Interoperability Program. Specifically, we are proposing to: (1) Eliminate requirement that, for the FY 2020 payment adjustment year, for an eligible hospital that has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period in CY 2019 must end before and the eligible hospital must successfully register for and attest to meaningful use no later than the October 1, 2019 deadline; (2) establish an EHR reporting period of a minimum of any continuous 90-day period in CY 2021 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program attesting to CMS; (3) require that the Medicare Promoting Interoperability Program measure actions must occur within the EHR reporting period beginning with the EHR reporting period in CY 2020; (4) revise the Query of PDMP measure to make it an optional measure worth 5 bonus points in CY 2020, remove the exclusions associated with this measure in CY 2020, require a yes/no response instead of a numerator and denominator for CY 2019 and CY 2020, and clearly state our intended policy that the measure is worth a full 5 bonus points in CY 2019 and CY 2020; (5) change the maximum points available for the e-Prescribing measure to 10 points beginning in CY 2020, in the event we finalize the proposed changes to the Query of PDMP measure; (6) remove the Verify Opioid Treatment Agreement measure beginning in CY 2020 and clearly state our intended policy that this measure is worth a full 5 bonus points in CY 2019; and (7) revise the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to more clearly

capture the previously established policy regarding CEHRT use. We are also proposing to amend our regulations to incorporate several of these proposals.

For CQM reporting under the Medicare and Medicaid Promoting Interoperability Programs, we are generally proposing to align our requirements with requirements under the Hospital IQR Program. Specifically, we are proposing to: (1) Adopt two opioid-related eCQMs (Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) and Hospital Harm—Opioid-Related Adverse Events eCQM) beginning with the reporting period in CY 2021; (2) extend current CQM reporting and submission requirements for the reporting periods in CY 2020 and CY 2021; and (3) establish CQM reporting and submission requirements for the reporting period in CY 2022, which would require all eligible hospitals and CAHs to report on the proposed Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) beginning with the reporting period in CY 2022.

We are seeking public comments on whether we should consider proposing to adopt in future rulemaking the Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) measure beginning with the reporting period in CY 2023, a measure which we are proposing to adopt under the Hospital IQR Program, and we are seeking information on a variety of issues regarding the future direction of the Medicare and Medicaid Promoting Interoperability Programs.

3. Summary of Costs and Benefits

• *Proposed Adjustment for MS–DRG Documentation and Coding Changes.* Section 414 of the MACRA replaced the single positive adjustment we intended to make in FY 2018 once the recoupment required by section 631 of the ATRA was complete with a 0.5 percentage point positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percentage point by section 15005 of the 21st Century Cures Act.) For FY 2020, we are proposing to make an adjustment of +0.5 percentage point to the standardized amount consistent with the MACRA.

• *Proposed Alternative Inpatient New Technology Add-On Payment Pathway for Transformative New Devices:* In this proposed rule, we are proposing an alternative inpatient new technology add-on payment pathway for a new medical device that is part of the FDA Breakthrough Devices Program and has received FDA marketing authorization, that is, received PMA approval, 510(k) clearance, or the granting of De Novo classification request.

Given the relatively recent introduction of FDA's Breakthrough Devices Program, there have not been any medical devices that were part of the Breakthrough Devices Program and received FDA marketing authorization and for which the applicant applied for a new technology add-on payment under the IPPS and was not approved. Therefore, it is not possible to quantify the impact of this proposal.

• *Proposed Changes to the Calculation of the Inpatient Hospital New Technology Add-On Payment:* The current calculation of the new technology add-on payment is based on the cost to hospitals for the new medical service or technology. Under existing § 412.88, if the costs of the discharge exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare makes an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology or medical service; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment. In this proposed rule, we are proposing to modify the current payment mechanism to increase the amount of the maximum add-on payment amount to 65 percent. Therefore, we are proposing that if the costs of a discharge involving a new technology exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare would make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

We estimate that if we finalize our proposals for the 9 technologies for which we are proposing to continue to make new technology add-on payments in FY 2020 and if we determine that all 17 of the FY 2020 new technology add-on payment applications meet the specified criteria for new technology add-on payments for FY 2020, this proposal, if finalized, would increase IPPS spending by approximately $110 million in FY 2020.

• *Proposed Changes to Address Wage Index Disparities Between High and Low Wage Index Hospitals.* As discussed in section III.N. of the preamble of this proposed rule, to help mitigate wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications under 42 CFR 412.103 in the rural floor, we are proposing to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and decreasing the wage index values of certain hospitals with high wage index values for budget neutrality purposes, as well as changing the calculation of the rural floor. We also are proposing a transition for hospitals experiencing significant decreases in their wage index values as a result of these proposed changes. We are proposing to make these changes in a budget neutral manner.

We are proposing to apply a budget neutrality adjustment to the standardized amount so that our proposed transition for hospitals that could be negatively impacted is implemented in a budget neutral manner.

• *Proposed Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care.* For FY 2020, we are proposing to update our estimates of the three factors used to determine uncompensated care payments. We are proposing to continue to use uninsured estimates produced by OACT as part of the development of the NHEA in the calculation of Factor 2. We also are proposing to use a single year of data on uncompensated care costs from Worksheet S–10 for FY 2015 to determine Factor 3 for FY 2020. In addition, we are seeking public comments on whether we should, due to changes in the reporting instructions that became effective for FY 2017, alternatively use a single year of Worksheet S–10 data from the FY 2017 cost reports, instead of the FY 2015 Worksheet S–10 data, to calculate Factor 3 for FY 2020. To determine the amount of uncompensated care for purposes of calculating Factor 3 for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, we are proposing to continue to use only data regarding low-income insured days for FY 2013.

We project that the amount available to distribute as payments for uncompensated care for FY 2020 would increase by approximately $216 million, as compared to our estimate of the uncompensated care payments that will be distributed in FY 2019. The payments have redistributive effects, based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are projected to be eligible to receive Medicare DSH payments, and the calculated payment amount is not directly tied to a hospital's number of discharges.

• *Proposed Update to the LTCH PPS Payment Rates and Other Payment Policies.* Based on the best available data for the 384 LTCHs in our database, we estimate that the proposed changes to the payment rates and factors that we present in the preamble of and Addendum to this proposed rule, which reflect the end of the transition of the statutory application of the site neutral payment rate and the proposed update to the LTCH PPS standard Federal payment rate for FY 2020, would result in an estimated increase in payments in FY 2020 of approximately $37 million.

• *Proposed Changes to the Hospital Readmissions Reduction Program.* For FY 2020 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. Overall, in this proposed rule, we estimate that 2,599 hospitals would have their base operating DRG payments reduced by their determined proxy FY 2020 hospital-specific readmission adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program would save approximately $550 million in FY 2020.

• *Value-Based Incentive Payments Under the Hospital VBP Program.* We estimate that there would be no net financial impact to the Hospital VBP Program for the FY 2020 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS–DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS–DRG payment amount reductions for the FY 2020 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2020 discharges is approximately $1.9 billion.

• *Proposed Changes to the HAC Reduction Program.* A hospital's Total HAC score and its ranking in comparison to other hospitals in any given year depend on several different factors. The FY 2020 program year is the first year in which we will implement our equal measure weights scoring methodology. Any significant impact due to the HAC Reduction Program proposed changes for FY 2020, including which hospitals will receive the adjustment, would depend on the actual experience of hospitals in the Program. We also are proposing to update the hourly wage rate associated with burden for CDC NHSN HAI validation under the HAC Reduction Program.

• *Proposed Changes to the Hospital Inpatient Quality Reporting (IQR) Program.* Across 3,300 IPPS hospitals, we estimate that our proposed changes for the Hospital IQR Program in this proposed rule would result in changes to the information collection burden compared to previously adopted requirements. The only proposal that would affect the information collection burden for the Hospital IQR Program is the proposal to adopt the Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) measure (NQF #2879) in a stepwise fashion, beginning with two voluntary reporting periods which would run from July 1, 2021 through June 30, 2022, and from July 1, 2022 through June 30, 2023, before requiring reporting of the measure for the reporting period that would run from July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination and for subsequent years. We estimate that the impact of this proposed change is a total collection of information burden increase of 2,211 hours and a total cost increase of approximately $83,266 for all participating IPPS hospitals annually.

• *Proposed Changes to the Medicare and Medicaid Promoting Interoperability Programs.* We believe that, overall, the proposals in this proposed rule would reduce burden, as described in detail in section X.B.9. of the preamble and Appendix A, section I.N. of this proposed rule.

B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment beginning on October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs)

receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2022. Through and including FY 2006, an MDH received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate was exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. For discharges occurring on or after October 1, 2007, but before October 1, 2022, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years).

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006 through September 30, 2015 all LTCHs were paid 100 percent of the Federal rate. Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, based on a rolling effective date that is linked to the date on which a given LTCH's Federal FY 2016 cost reporting period begins, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the

various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation That Would Be Implemented in This Proposed Rule

1. Pathway for SGR Reform Act of 2013 (Pub. L. 113–67)

The Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) introduced new payment rules in the LTCH PPS. Under section 1206 of this law, discharges in cost reporting periods beginning on or after October 1, 2015, under the LTCH PPS, receive payment under a site neutral rate unless the discharge meets certain patient-specific criteria. In this proposed rule, we are proposing to continue to update certain policies that implemented provisions under section 1206 of the Pathway for SGR Reform Act.

2. Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185)

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), enacted on October 6, 2014, made a number of changes that affect the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). In this proposed rule, we are proposing to continue to implement portions of section 1899B of the Act, as added by section 2(a) of the IMPACT Act, which, in part, requires LTCHs, among other post-acute care providers, to report standardized patient assessment data, data on quality measures, and data on resource use and other measures.

3. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA, Pub. L. 114–10) specifies a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. These adjustments follow the recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring from FYs 2014 through 2017 to fully offset $11 billion, in accordance with section 631 of the ATRA. The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.

4. The 21st Century Cures Act (Pub. L. 114–255)

The 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, contained the following provision affecting payments under the Hospital Readmissions Reduction Program, which we are proposing to continue to implement in this proposed rule:

- Section 15002, which amended section 1886(q)(3) of the Act by adding subparagraphs (D) and (E), which requires the Secretary to develop a methodology for calculating the excess readmissions adjustment factor for the Hospital Readmissions Reduction Program based on cohorts defined by the percentage of dual-eligible patients (that is, patients who are eligible for both Medicare and full-benefit Medicaid coverage) cared for by a hospital. In this proposed rule, we are proposing to continue to implement changes to the payment adjustment factor to assess penalties based on a hospital's performance, relative to other hospitals treating a similar proportion of dual-eligible patients.

D. Summary of the Provisions of This Proposed Rule

In this proposed rule, we set forth proposed payment and policy changes to the Medicare IPPS for FY 2020 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2020.

Below is a general summary of the changes that we are proposing to make in this proposed rule.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of this proposed rule, we include—

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2020.
- Proposed adjustment to the standardized amounts under section 1886(d) of the Act for FY 2020 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA.
- Proposed recalibration of the MS–DRG relative weights.
- A discussion of the proposed FY 2020 status of new technologies approved for add-on payments for FY 2019 and a presentation of our evaluation and analysis of the FY 2020 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting).
- A request for public comments on the substantial clinical improvement criterion used to evaluate applications for both the IPPS new technology add-on payments and the OPPS transitional pass-through payment for devices, and a discussion of potential revisions that we are considering adopting as final policies related to the substantial clinical improvement criterion for applications received beginning in FY 2020 for the IPPS (that is, for FY 2021 and later new technology add-on payments) and beginning in CY 2020 for the OPPS.
- A proposed alternative IPPS new technology add-on payment pathway for certain transformative new devices.
- Proposed changes to the calculation of the IPPS new technology add-on payment.

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to this proposed rule, we are proposing to make revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but are not limited to, the following:

- The proposed FY 2020 wage index update using wage data from cost reporting periods beginning in FY 2016.
- Proposals to address wage index disparities between high and low wage index hospitals.
- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for FY 2020 based on the 2016 Occupational Mix Survey.
- Proposed application of the rural floor and the frontier State floor.
- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposed change to Lugar county assignments.
- Proposed adjustment to the wage index for acute care hospitals for FY 2020 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Proposed labor-related share for the proposed FY 2020 wage index.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section IV. of the preamble of this proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42

CFR parts 412 and 413, including the following:

- Proposed changes to MS–DRGs subject to the postacute care transfer policy and special payment policy.
- Proposed changes to the inpatient hospital update for FY 2020.
- Proposed conforming changes to the regulations for the low-volume hospital payment adjustment policy.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- The statutorily required IME adjustment factor for FY 2020.
- Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.
- A request for public comments on PRRB appeals related to a hospital's Medicaid fraction in the DSH payment adjustment calculation.
- Proposed changes to the policies for payment adjustments under the Hospital Readmissions Reduction Program based on hospital readmission measures and the process for hospital review and correction of those rates for FY 2020.
- Proposed changes to the requirements and provision of value-based incentive payments under the Hospital Value-Based Purchasing Program.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2020.
- Proposed changes related to CAHs as nonproviders for direct GME and IME payment purposes.
- Discussion of and proposals relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2020.

4. Proposed FY 2020 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to this proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2020.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of this proposed rule, we discuss—

- Proposed changes to payments to certain excluded hospitals for FY 2020.
- Proposed change related to CAH payment for ambulance services.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

6. Proposed Changes to the LTCH PPS

In section VII. of the preamble of this proposed rule, we set forth—

- Proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2020.
- Proposed payment adjustment for discharges of LTCHs that do not meet the applicable discharge payment percentage.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section VIII. of the preamble of this proposed rule, we address—

- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program.
- Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
- Proposed changes to the requirements under the LTCH Quality Reporting Program (LTCH QRP).
- Proposed changes to requirements pertaining to eligible hospitals and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs.

8. Provider Reimbursement Review Board Appeals

In section XI. of the preamble of this proposed rule, we discuss the growing number of Provider Reimbursement Review Board appeals made by providers and the action initiatives that are being implemented with the goal to: decrease the number of appeals submitted; decrease the number of appeals in inventory; reduce the time to resolution; and increase customer satisfaction.

9. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum to this proposed rule, we set forth the proposed changes to the amounts and factors for determining the proposed FY 2020 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We are proposing to establish the threshold amounts for outlier cases, including a proposed change to the methodology for calculating those threshold amounts for FY 2020 to incorporate a projection of outlier payment reconciliations. In addition, in section IV. of the Addendum to this proposed rule, we address the update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2020 for certain hospitals excluded from the IPPS.

10. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2020 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2020. We are proposing to establish the adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

11. Impact Analysis

In Appendix A of this proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, CAHs, LTCHs, and PCHs.

12. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2020 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

13. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2019 recommendations concerning hospital inpatient payment policies addressed the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We address these

recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2019 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at: *http://www.medpac.gov*.

E. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) and CMS work collaboratively to advance interoperability across settings of care, including post-acute care.

To further interoperability in post-acute care, we developed a Data Element Library (DEL) to serve as a publicly available centralized, authoritative resource for standardized data elements and their associated mappings to health IT standards. The DEL furthers CMS' goal of data standardization and interoperability, which is also a goal of the IMPACT Act. These interoperable data elements can reduce provider burden by allowing the use and exchange of health care data, support provider exchange of electronic health information for care coordination, person-centered care, and support real-time, data driven, clinical decision making. Standards in the Data Element Library (*https://del.cms.gov/*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2019 ISA is available at: *https://www.healthit.gov/isa*.

The 21st Century Cures Act (the Cures Act) (Pub. L. 114–255, enacted December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. In an important provision, Congress defined ''information blocking'' as practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information, and established new authority for HHS to discourage these practices. In March 2019, ONC and CMS published the proposed rules, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (84 FR 7424 through 7610) and ''Interoperability and Patient Access'' (84 FR 7610 through 7680), to promote secure and more immediate access to health information for patients and health care providers through the implementation of information blocking provisions of the Cures Act and the use of standardized application programming interfaces (APIs) that enable easier access to electronic health information. These two proposed rules are open for public comments at: *www.regulations.gov*.

We invite providers to learn more about these important developments and how they are likely to affect hospitals paid under the IPPS and the LTCH PPS.

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. MS–DRG Reclassifications

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2019 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085, and 83 FR 41158 through 41258, respectively).

C. Adoption of the MS–DRGs in FY 2008

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

D. Proposed FY 2020 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90 and the Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percentage points to the national standardized amount. We provided for phasing in this −4.8 percentage point adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percentage points for FY 2008, −1.8 percentage points for FY 2009, and −1.8 percentage points for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and

QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percentage point for FY 2008 and −0.9 percentage point for FY 2009.

As discussed in prior year rulemakings, and most recently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56780 through 56782), we implemented a series of adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90, based on a retrospective review of FY 2008 and FY 2009 claims data. We completed these adjustments in FY 2013 but indicated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53275) that delaying full implementation of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated, and that these overpayments could not be recovered under Public Law 110–90.

In addition, as discussed in prior rulemakings and most recently in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38008 through 38009), section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.

2. Adjustments Made for FY 2018 and FY 2019 as Required Under Section 414 of Public Law 114–10 (MACRA) and Section 15005 of Public Law 114–255

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023. In the FY 2017 rulemaking, we indicated that we would address the adjustments for FY 2018 and later fiscal years in future rulemaking. Section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted on December 13, 2016, amended section 7(b)(1)(B) of the TMA, as amended by section 631 of the ATRA and section 414 of the MACRA, to reduce the adjustment for FY 2018 from a 0.5 percentage point positive adjustment to a 0.4588 percentage point positive adjustment. As we discussed in the FY 2018 rulemaking, we believe the directive under section 15005 of Public Law 114–255 is clear. Therefore, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38009) for FY 2018, we implemented the required +0.4588 percentage point adjustment to the standardized amount. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41157), consistent with the requirements of section 414 of the MACRA, we implemented a 0.5 percentage point positive adjustment to the standardized amount for FY 2019. We indicated that both the FY 2018 and FY 2019 adjustments were permanent adjustments to payment rates. We also stated that we plan to propose future adjustments required under section 414 of the MACRA for FYs 2020 through 2023 in future rulemaking.

3. Proposed Adjustment for FY 2020

Consistent with the requirements of section 414 of the MACRA, we are proposing to implement a 0.5 percentage point positive adjustment to the standardized amount for FY 2020. This would constitute a permanent adjustment to payment rates. We plan to propose future adjustments required under section 414 of the MACRA for FYs 2021 through 2023 in future rulemaking.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS–DRGs. We also refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785 through 56787) for a detailed discussion of the history of changes to the number of cost centers used in calculating the DRG relative weights. Since FY 2014, we have calculated the IPPS MS–DRG relative weights using 19 CCRs, which now include distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

2. Discussion of Policy for FY 2020

Consistent with our established policy, we are calculating the proposed MS–DRG relative weights for FY 2020 using two data sources: The MedPAR file as the claims data source and the HCRIS as the cost report data source. We adjust the charges from the claims to costs by applying the 19 national average CCRs developed from the cost reports. The description of the calculation of the proposed 19 CCRs and the proposed MS–DRG relative weights for FY 2020 is included in section II.G. of the preamble to this FY 2020 IPPS/LTCH PPS proposed rule. As we did with the FY 2019 IPPS/LTCH PPS final rule, for this FY 2020 proposed rule, we are providing the version of the HCRIS from which we calculated these proposed 19 CCRs on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled ''FY 2020 IPPS Proposed Rule Home Page'' or ''Acute Inpatient Files for Download.''

F. Proposed Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for Proposed FY 2020 MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and Reporting. For a detailed discussion of the conversion of the MS–DRGs to ICD–10, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56789).

b. Basis for Proposed FY 2020 MS–DRG Updates

CMS has previously encouraged input from our stakeholders concerning the annual IPPS updates when that input was made available to us by December

7 of the year prior to the next annual proposed rule update. As discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38010), as we work with the public to examine the ICD–10 claims data used for updates to the ICD–10 MS DRGs, we would like to examine areas where the MS–DRGs can be improved, which will require additional time for us to review requests from the public to make specific updates, analyze claims data, and consider any proposed updates. Given the need for more time to carefully evaluate requests and propose updates, we changed the deadline to request updates to the MS–DRGs to November 1 of each year. This will provide an additional 5 weeks for the data analysis and review process. Interested parties had to submit any comments and suggestions for FY 2020 by November 1, 2018, and should submit any comments and suggestions for FY 2021 by November 1, 2019 via the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov*. The comments that were submitted in a timely manner for FY 2020 are discussed in this section of the preamble of this proposed rule. As we discuss in the sections that follow, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD–10, some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change. We note in the discussion that follows those topics for which further research and analysis are required, and which we will continue to consider in connection with future rulemaking.

Following are the changes that we are proposing to the MS–DRGs for FY 2020. We are inviting public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in this proposed rule. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. In other cases, we are proposing to maintain the existing MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. For this FY 2020 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2018 update of the FY 2018 MedPAR file, which contains hospital bills received through September 30, 2018, for discharges occurring through September 30, 2018. In our discussion of the proposed MS–DRG reclassification changes, we refer to these claims data as the ''September 2018 update of the FY 2018 MedPAR file.''

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In our examination of the claims data, we apply the following criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG is warranted:

- A reduction in variance of costs of at least 3 percent;
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup;
- At least 500 cases are in the CC or MCC subgroup;
- There is at least a 20-percent difference in average costs between subgroups; and
- There is a $2,000 difference in average costs between subgroups.

In order to warrant creation of a CC or MCC subgroup within a base MS–DRG, the subgroup must meet all five of the criteria.

2. Pre-MDC

a. Peripheral ECMO

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41166 through 41169), we discussed a request we received to review cases reporting the use of extracorporeal membrane oxygenation (ECMO) in combination with the insertion of a percutaneous short-term external heart assist device. We also noted that a separate request to create a new ICD–10–PCS procedure code specifically for percutaneous ECMO was discussed at the March 6–7, 2018 ICD–10 Coordination and Maintenance Committee Meeting for which we finalized the creation of three new procedure codes to identify and describe different types of ECMO treatments currently being utilized. These three new procedure codes were included in the FY 2019 ICD–10–PCS procedure codes files (which are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/2019-ICD-10-PCS.html*) and were made publicly available in May 2018. We received recommendations from commenters on suggested MS–DRG assignments for the two new procedure codes that uniquely identify percutaneous (peripheral) ECMO, including assignment to MS–DRG 215 (Other Heart Assist System Implant), or to Pre-MDC MS–DRG 004 (Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedure) specifically for the new procedure code describing percutaneous veno-venous (VV) ECMO or an alternate MS–DRG within MDC 4 (Diseases and Disorders of the Respiratory System). In our response, we noted that because these codes were not finalized at the time of the proposed rule, there were no proposed MDC or MS–DRG assignments or O.R. and non-O.R. designations for these new procedure codes and they were not reflected in Table 6B.—New Procedure Codes (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) associated with the FY 2019 IPPS/LTCH PPS proposed rule.

We further noted that, consistent with our annual process of assigning new procedure codes to MDCs and MS–DRGs, and designating a procedure as an O.R. or non-O.R. procedure, we reviewed the predecessor procedure code assignment. For the reasons discussed in the FY 2019 IPPS/LTCH PPS final rule, our clinical advisors did not support assigning the new procedure codes for the percutaneous (peripheral) ECMO procedures to the same MS–DRG as the predecessor code for open (central) ECMO in pre-MDC MS–DRG 003.

Effective with discharges occurring on and after October 1, 2018, the three ECMO procedure codes and their corresponding MS–DRG assignments are as shown in the following table.

ICD–10–PCS code	Code description	MS–DRG	MS–DRG description
5A1522F	Extracorporeal Oxygenation, Membrane, Central.	Pre-MDC MS–DRG 003	ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure.
5A1522G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial.	MS–DRG 207	Respiratory System Diagnosis with Ventilator Support >96 Hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO).
		MS–DRG 291	Heart Failure and Shock with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO).
		MS–DRG 296	Cardiac Arrest, Unexplained with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO).
		MS–DRG 870	Septicemia Or Severe Sepsis with Mechanical Ventilation >96 Hours Or Peripheral Extracorporeal Membrane Oxygenation (ECMO).
5A1522H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous.	MS–DRG 207	Respiratory System Diagnosis with Ventilator Support >96 Hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO).
		MS–DRG 291	Heart Failure and Shock with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO).
		MS–DRG 296	Cardiac Arrest, Unexplained with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO).
		MS–DRG 870	Septicemia Or Severe Sepsis with Mechanical Ventilation >96 Hours Or Peripheral Extracorporeal Membrane Oxygenation (ECMO).

After publication of the FY 2019 IPPS/LTCH PPS final rule, we received comments and feedback from stakeholders expressing concern with the MS–DRG assignments for the two new procedure codes describing peripheral ECMO. Specifically, these stakeholders stated that: (1) The MS–DRG assignments for ECMO should not be based on how the patient is cannulated (open versus peripheral) because most of the costs for both central and peripheral ECMO can be attributed to the severity of illness of the patient; (2) there was a lack of opportunity for public comment on the finalized MS–DRG assignments; (3) patient access to ECMO treatment and programs is now at risk because of inadequate payment; and (4) CMS did not appear to have access to enough patient data to evaluate for appropriate MS–DRG assignment consideration. They also stated that the new procedure codes do not account for an open cut-down approach that may be performed on a peripheral vessel during a peripheral ECMO procedure. These stakeholders recommended that, consistent with the usual process of assigning new procedure codes to the same MS–DRG as the predecessor code, the MS–DRG assignment for peripheral ECMO procedures should be revised to allow assignment of peripheral ECMO procedures to Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure). They stated that this revision would also allow for the collection of further claims data for patients treated with ECMO and assist in determining the appropriateness of any future modifications in MS–DRG assignment.

We also received feedback from a few stakeholders that, for some cases involving peripheral ECMO, the current designation provides compensation that these stakeholders believe is ''reasonable'' (for example, for peripheral ECMO in certain patients admitted with acute respiratory failure and sepsis). Some of these stakeholders agreed with CMS that once claims data become available, the volume, length of stay and cost data of claims with these new codes can be examined to determine if modifications to MS–DRG assignment or O.R. and non-O.R. designation are warranted. However, some of these stakeholders also expressed concerns that the current assignments and designation do not appropriately compensate for the resources used when peripheral ECMO is used to treat certain patients (for example, patients who are admitted with cardiac arrest and cardiogenic shock of known cause or patients admitted with a different principal diagnosis or patients who develop a diagnosis after admission that requires ECMO). These stakeholders stated that the current MS–DRG assignments for such cases involving peripheral ECMO do not provide sufficient payment and do not fully consider the severity of illness of the patient and the level of resources involved in treating such patients, such as surgical team, general anesthesia, and other ECMO support such as specialized monitoring.

With regard to stakeholders' concerns that we did not allow the opportunity for public comment on the MS–DRG assignment for the three new procedure codes that describe central and peripheral ECMO, as noted above and as explained in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41168), these new procedure codes were not finalized at the time of the proposed rule. We note that although there were no proposed MDC or MS–DRG assignment or O.R. and non-O.R. designations for these three new procedure codes, we did, in fact, review and respond to comments on the recommended MDC and MS–DRG assignments and O.R./non-O.R. designations in the final rule (83 FR 41168 through 41169). For FY 2019, consistent with our annual process of assigning new procedure codes to MDCs and MS–DRGs and designating a procedure as an O.R. or non-O.R. procedure, we reviewed the predecessor procedure code assignments. Upon completing the review, our clinical advisors did not support assigning the two new ICD–10–PCS procedure codes for peripheral ECMO procedures to the same MS–DRG as the predecessor code for open (central) ECMO procedures. Further, our clinical advisors also did not agree with designating peripheral

ECMO procedures as O.R. procedures because they stated that these procedures are less resource intensive compared to open ECMO procedures.

As noted, our annual process for assigning new procedure codes involves review of the predecessor procedure code's MS–DRG assignment. However, this process does not automatically result in the new procedure code being assigned (or proposed for assignment) to the same MS–DRG as the predecessor code. There are several factors to consider during this process that our clinical advisors take into account. For example, in the absence of volume, length of stay, and cost data, they may consider the specific service, procedure, or treatment being described by the new procedure code, the indications, treatment difficulty, and the resources utilized. We have continued to consider how these and other factors may apply in the context of classifying procedures under the ICD–10 MS–DRGs, including with regard to the specific concerns raised by stakeholders.

In the absence of claims data for the new ICD–10–PCS procedure codes describing peripheral ECMO, we analyzed claims data from the September 2018 update of the FY 2018 MedPAR file for cases reporting the predecessor ICD–10–PCS procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous) in Pre-MDC MS–DRG 003, including those cases reporting secondary diagnosis MCC and CC conditions, that were grouped under the ICD–10 MS–DRG Version 35 GROUPER. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 003—All cases	14,456	29.6	$122,168
MS–DRG 003—Cases reporting procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous)	2,086	20.2	128,168
MS–DRG 003—Cases reporting procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous) with MCC	2,000	20.7	131,305
MS–DRG 003—Cases reporting procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous) with CC	79	7.6	58,231

The total number of cases reported in MS–DRG 003 was 14,456, with an average length of stay of 29.6 days and average costs of $122,168. For the cases reporting procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous), there was a total of 2,086 cases, with an average length of stay of 20.2 days and average costs of $128,168. For the cases reporting procedure code 5A15223 with an MCC, there was a total of 2,000 cases, with an average length of stay of 20.7 days and average costs of $131,305. For the cases reporting procedure code 5A15223 with a CC, there was a total of 79 cases, with an average length of stay of 7.6 days and average costs of $58,231.

Our clinical advisors reviewed these data and noted that the average length of stay for the cases reporting ECMO with procedure code 5A15223 of 20.2 days may not necessarily be a reliable indicator of resources that can be attributed to ECMO treatment. Our clinical advisors believed that a more appropriate measure of resource consumption for ECMO would be the number of hours or days that a patient was specifically receiving ECMO treatment, rather than the length of hospital stay. However, they noted that this information is not currently available in the claims data. Our clinical advisors also stated that the average costs of $128,168 for the cases reporting ECMO with procedure code 5A15223 are not necessarily reflective of the resources utilized for ECMO treatment alone, as the average costs represent a combination of factors, including the principal diagnosis, any secondary diagnosis CC and/or MCC conditions necessitating initiation of ECMO, and potentially any other procedures that may be performed during the hospital stay. Our clinical advisors recognized that patients who require ECMO treatment are severely ill and recommended we review the claims data to identify the number (frequency) and types of principal and secondary diagnosis CC and/or MCC conditions that were reported among the 2,086 cases reporting procedure code 5A15223. Our findings are shown in the following tables for the top 10 principal diagnosis codes, followed by the top 10 secondary diagnosis MCC and secondary diagnosis CC conditions that were reported within the claims data with procedure code 5A15223.

TOP 10 PRINCIPAL DIAGNOSIS CODES REPORTED WITH PROCEDURE CODE 5A1223

[Extracorporeal membrane oxygenation, continuous]

ICD–10–CM code	Description	Number of times reported
A41.9	Sepsis, unspecified organism	145
I21.4	Non-ST elevation (NSTEMI) myocardial infarction	137
I35.0	Nonrheumatic aortic (valve) stenosis	81
J84.112	Idiopathic pulmonary fibrosis	68
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris	55
J96.01	Acute respiratory failure with hypoxia	52
I21.09	STEMI involving other coronary artery of anterior wall	49
I25.10	Atherosclerotic heart disease of native coronary artery w/o angina pectoris	48
I13.0	Hypertensive heart & chronic kidney disease w heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease.	46
I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall	43

TOP 10 SECONDARY DIAGNOSIS MCC CONDITIONS REPORTED WITH PROCEDURE CODE 5A1223

[Extracorporeal membrane oxygenation, continuous]

ICD–10–CM code	Description	Number of times reported	Average length of stay	Average costs
A41.9	Sepsis, unspecified organism	322	29.7	$186,055
E43	Unspecified severe protein-calorie malnutrition	220	41.5	213,742
G93.40	Encephalopathy, unspecified	217	27.2	165,193
J18.9	Pneumonia, unspecified organism	220	23.5	150,242
J96.01	Acute respiratory failure with hypoxia	944	17.9	122,614
J96.02	Acute respiratory failure with hypercapnia	220	20.9	139,511
K72.00	Acute and subacute hepatic failure without coma	524	19	140,878
N17.0	Acute kidney failure with tubular necrosis	741	26.2	162,583
R57.0	Cardiogenic shock	448	27.7	153,878
R65.21	Severe sepsis with septic shock	504	29.7	177,992

TOP 10 SECONDARY DIAGNOSIS CC CONDITIONS REPORTED WITH PROCEDURE CODE 5A1223

[Extracorporeal membrane oxygenation, continuous]

ICD–10–CM code	Description	Number of times reported	Average length of stay	Average costs
D62	Acute posthemorrhagic anemia	1,139	21.8	$144,033
D68.9	Coagulation defect, unspecified	402	20.5	138,417
E87.0	Hyperosmolality and hypernatremia	585	26.6	162,028
E87.1	Hypo-osmolality and hyponatremia	316	26.1	151,824
E87.2	Acidosis	937	17.3	120,881
E87.4	Mixed disorder of acid-base balance	268	26	150,257
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease.	314	18.4	121,962
I47.2	Ventricular tachycardia	384	17.5	123,383
J98.11	Atelectasis	273	26.9	158,812
N17.9	Acute kidney failure, unspecified	757	18.5	122,180

These data show that the conditions reported for these patients requiring treatment with ECMO and reported with predecessor ICD–10–PCS procedure code 5A1223 represent a greater severity of illness, present greater treatment difficulty, have poorer prognoses, and have a greater need for intervention. While the data analysis was based on the conditions reported with the predecessor ICD–10–PCS procedure code 5A1223 (Extracorporeal membrane oxygenation, continuous), our clinical advisors believe the data may provide an indication of how cases reporting the new procedure codes describing peripheral (percutaneous) ECMO may be represented in future claims data with regard to indications for treatment, a patient's severity of illness, resource utilization, and treatment difficulty.

Based on the results of our data analysis and further review of the cases reporting ECMO, including consideration of the stakeholders' concerns that the MS–DRG assignments for ECMO procedures should not be based on the method of cannulation, our clinical advisors agree that resource consumption for both central and peripheral ECMO cases can be primarily attributed to the severity of illness of the patient, and that the method of cannulation is less relevant when considering the overall resources required to treat patients on ECMO. Specifically, our clinical advisors noted that consideration of resource consumption for cases reporting the use of ECMO may extend well beyond the duration of time that a patient was actively receiving ECMO treatment, which may range anywhere from less than 24 hours to 10 days or more. As noted above, in the absence of unique procedure codes that specify the duration of time that a patient was receiving ECMO treatment, we cannot ascertain from the claims data the resource use specifically attributable to treatment with ECMO during a hospital stay. However, when reviewing consumption of hospital resources for the cases in which ECMO was reported during a hospital stay, the claims data clearly show that the patients placed on ECMO typically have multiple MCC and CC conditions. These data provide additional information on the expanding indications for ECMO treatment as well as an indication of the complexities and the treatment difficulty associated with these patients. While our clinical advisors continue to believe that central (open) ECMO may be more resource intensive and carries significant risks for complications, including bleeding, infection, and vessel injury because it requires an incision along the sternum (sternotomy) and is performed for open heart surgery, they believe that the subset of patients who require treatment with ECMO, regardless of the cannulation method, would be similar in terms of overall hospital resource consumption. We also note that while we do not yet have Medicare claims data to evaluate the new peripheral ECMO procedure codes, review of limited registry data provided by stakeholders for patients treated with a reported peripheral ECMO procedure did not contradict that costs for peripheral ECMO appear to be similar to the costs of overall resources required to treat patients on ECMO (regardless of method of cannulation) and appear to be attributable to the severity of illness of the patient.

With regard to stakeholders who stated that the two new procedure codes do not account for an open cut-down approach that may be performed on a peripheral vessel during a peripheral ECMO procedure, we note that a request and proposal to create ICD–10–PCS codes to differentiate between peripheral vessel percutaneous and peripheral vessel open cutdown

according to the indication (VA or VV) for ECMO was discussed at the March 5–6, 2019 ICD–10 Coordination and Maintenance Committee meeting. We refer readers to the website at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html* for the committee meeting materials and discussion regarding this proposal. We also note that, in this same proposal, another coding option to add duration values to allow the reporting of the number of hours or the number of days a patient received ECMO during the stay was also made available for public comment.

Upon further review and consideration of peripheral ECMO procedures, including the indications, treatment difficulty, and the resources utilized, for the reasons discussed above, our clinical advisors support the assignment of the new ICD–10–PCS procedure codes for peripheral ECMO procedures to the same MS–DRG as the predecessor code for open (central) ECMO procedures for FY 2020. Therefore, based on our review, including consideration of the comments and input from our clinical advisors, we are proposing to reassign the following procedure codes describing peripheral ECMO procedures from their current MS–DRG assignments to Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure) as shown in the table below. If this proposal is finalized, we also would make conforming changes to the titles for MS–DRGs 207, 291, 296, and 870 to no longer reflect the ''or Peripheral Extracorporeal Membrane Oxygenation (ECMO)'' terminology in the title. We note that this proposal includes maintaining the designation of these peripheral ECMO procedures as non-O.R. Therefore, if finalized, the procedures would be defined as non-O.R. affecting the MS–DRG assignment for Pre-MDC MS–DRG 003.

ICD–10–PCS code	Code description	Current MS–DRG	Proposed MS–DRG
5A1522G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial.	MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support >96 Hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO)).	Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure).
		MS–DRG 291 (Heart Failure and Shock with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO)).	Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure).
		MS–DRG 296 (Cardiac Arrest, Unexplained with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO)).	Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure).
		MS–DRG 870 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO)).	Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure).
5A1522H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous.	MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support >96 Hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO)).	Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure).
		MS–DRG 291 (Heart Failure and Shock with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO)).	Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure).
		MS–DRG 296 (Cardiac Arrest, Unexplained with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO)).	Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure).
		MS–DRG 870 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO)).	Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure).

b. Allogeneic Bone Marrow Transplant

We received a request to create new MS–DRGs for cases that would identify patients who undergo an allogeneic hematopoietic cell transplant (HCT) procedure. The requestor asked us to split MS–DRG 014 (Allogeneic Bone Marrow Transplant) into two new MS–DRGs and assign cases to the recommended new MS–DRGs according to the donor source, with cases for allogeneic *related* matched donor source assigned to one MS–DRG and cases for allogeneic *unrelated* matched donor source assigned to the other MS–DRG. The requestor stated that by creating two new MS–DRGs for allogeneic related and allogeneic unrelated donor source, respectively, the MS–DRGs would more appropriately recognize the clinical characteristics and cost differences in allogeneic HCT cases.

The requestor stated that allogeneic related and allogeneic unrelated HCT cases are clinically different and have significantly different donor search and cell acquisition charges. According to the requestor, 70 percent of patients do not have a matched sibling donor (that is, an allogeneic related matched donor) in their family. The requestor also stated that this rate is higher for Medicare beneficiaries. According to the requestor, the current payment for allogeneic HCT cases is inadequate and affects patient's access to care.

The requestor performed its own analysis and stated that it found the average costs for HCT cases reporting revenue code 0815 (Stem cell acquisition) alone or revenue code 0819 (Other organ acquisition) in combination with revenue code 0815 with one of the ICD–10–PCS procedure

codes for allogeneic unrelated donor source were significantly higher than the average costs for HCT cases reporting revenue code 0815 alone or both revenue codes 0815 and 0819 in combination with one of the ICD–10–PCS procedure codes for allogeneic related donor source. Further, the requestor reported that, according to its analysis, the average costs for HCT cases reporting revenue code 0815 alone or both revenue codes 0815 and 0819 in combination with one of the ICD–10–PCS procedure codes for unspecified allogeneic donor source were also significantly higher than the average costs for HCT cases reporting the ICD–10–PCS procedure codes for allogeneic related donor source. The requestor suggested that cases reporting the unspecified donor source procedure code are highly likely to represent unrelated donors, and recommended that, if the two new MS–DRGs are created as suggested, the cases reporting the procedure codes for unspecified donor source be included in the suggested new ''unrelated donor'' MS–DRG. The requestor also suggested that CMS apply a code edit through the inpatient Medicare Code Editor (MCE), similar to the edit in the Integrated Outpatient Code Editor (I/OCE) which requires reporting of revenue code 0815 on the claim with the appropriate procedure code or the claim may be subject to being returned to the provider.

The ICD–10–PCS procedure codes assigned to MS–DRG 014 that identify related, unrelated and unspecified donor source for an allogeneic HCT are shown in the following table.

ICD–10–PCS code	Code description
30230G2	Transfusion of allogeneic related bone marrow into peripheral vein, open approach.
30230G3	Transfusion of allogeneic unrelated bone marrow into peripheral vein, open approach.
30230G4	Transfusion of allogeneic unspecified bone marrow into peripheral vein, open approach.
30230X2	Transfusion of allogeneic related cord blood stem cells into peripheral vein, open approach.
30230X3	Transfusion of allogeneic unrelated cord blood stem cells into peripheral vein, open approach.
30230X4	Transfusion of allogeneic unspecified cord blood stem cells into peripheral vein, open approach.
30230Y2	Transfusion of allogeneic related hematopoietic stem cells into peripheral vein, open approach.
30230Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into peripheral vein, open approach.
30230Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into peripheral vein, open approach.
30233G2	Transfusion of allogeneic related bone marrow into peripheral vein, percutaneous approach.
30233G3	Transfusion of allogeneic unrelated bone marrow into peripheral vein, percutaneous approach.
30233G4	Transfusion of allogeneic unspecified bone marrow into peripheral vein, percutaneous approach.
30233X2	Transfusion of allogeneic related cord blood stem cells into peripheral vein, percutaneous approach.
30233X3	Transfusion of allogeneic unrelated cord blood stem cells into peripheral vein, percutaneous approach.
30233X4	Transfusion of allogeneic unspecified cord blood stem cells into peripheral vein, percutaneous approach.
30233Y2	Transfusion of allogeneic related hematopoietic stem cells into peripheral vein, percutaneous approach.
30233Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into peripheral vein, percutaneous approach.
30233Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into peripheral vein, percutaneous approach.
30240G2	Transfusion of allogeneic related bone marrow into central vein, open approach.
30240G3	Transfusion of allogeneic unrelated bone marrow into central vein, open approach.
30240G4	Transfusion of allogeneic unspecified bone marrow into central vein, open approach.
30240X2	Transfusion of allogeneic related cord blood stem cells into central vein, open approach.
30240X3	Transfusion of allogeneic unrelated cord blood stem cells into central vein, open approach.
30240X4	Transfusion of allogeneic unspecified cord blood stem cells into central vein, open approach.
30240Y2	Transfusion of allogeneic related hematopoietic stem cells into central vein, open approach.
30240Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into central vein, open approach.
30240Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into central vein, open approach.
30243G2	Transfusion of allogeneic related bone marrow into central vein, percutaneous approach.
30243G3	Transfusion of allogeneic unrelated bone marrow into central vein, percutaneous approach.
30243G4	Transfusion of allogeneic unspecified bone marrow into central vein, percutaneous approach.
30243X2	Transfusion of allogeneic related cord blood stem cells into central vein, percutaneous approach.
30243X3	Transfusion of allogeneic unrelated cord blood stem cells into central vein, percutaneous approach.
30243X4	Transfusion of allogeneic unspecified cord blood stem cells into central vein, percutaneous approach.
30243Y2	Transfusion of allogeneic related hematopoietic stem cells into central vein, percutaneous approach.
30243Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into central vein, percutaneous approach.
30243Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into central vein, percutaneous approach.
30250G1	Transfusion of nonautologous bone marrow into peripheral artery, open approach.
30250X1	Transfusion of nonautologous cord blood stem cells into peripheral artery, open approach.
30250Y1	Transfusion of nonautologous hematopoietic stem cells into peripheral artery, open approach.
30253G1	Transfusion of nonautologous bone marrow into peripheral artery, percutaneous approach.
30253X1	Transfusion of nonautologous cord blood stem cells into peripheral artery, percutaneous approach.
30253Y1	Transfusion of nonautologous hematopoietic stem cells into peripheral artery, percutaneous approach.
30260G1	Transfusion of nonautologous bone marrow into central artery, open approach.
30260X1	Transfusion of nonautologous cord blood stem cells into central artery, open approach.
30260Y1	Transfusion of nonautologous hematopoietic stem cells into central artery, open approach.
30263G1	Transfusion of nonautologous bone marrow into central artery, percutaneous approach.
30263X1	Transfusion of nonautologous cord blood stem cells into central artery, percutaneous approach.
30263Y1	Transfusion of nonautologous hematopoietic stem cells into central artery, percutaneous approach.

We examined claims data from the September 2018 update of the FY 2018 MedPAR file for MS–DRG 014 and identified the subset of cases within MS–DRG 014 reporting procedure codes for allogeneic HCT related donor source, allogeneic HCT unrelated donor source, and allogeneic HCT unspecified donor source, respectively. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 014—All cases	854	28.2	$91,446
MS–DRG 014—Cases reporting allogeneic HCT related donor source	292	29.5	87,444
MS–DRG 014—Cases reporting allogeneic HCT unrelated donor source	466	27.9	95,146
MS–DRG 014—Cases reporting allogeneic HCT unspecified donor source	90	26.2	90,945

The total number of cases reported in MS–DRG 014 was 854, with an average length of stay of 28.2 days and average costs of $91,446. For the subset of cases reporting procedure codes for allogeneic HCT related donor source, there were a total of 292 cases with an average length of stay of 29.5 days and average costs of $87,444. For the subset of cases reporting procedure codes for allogeneic HCT unrelated donor source, there was a total of 466 cases with an average length of stay of 27.9 days and average costs of $95,146. For the subset of cases reporting procedure codes for allogeneic HCT unspecified donor source, there was a total of 90 cases with an average length of stay of 26.2 days and average costs of $90,945.

Based on the analysis described above, the current MS–DRG assignment for the cases in MS–DRG 014 that identify patients who undergo an allogeneic HCT procedure, regardless of donor source, appears appropriate. The data analysis reflects that each subset of cases reporting a procedure code for an allogeneic HCT procedure (that is, related, unrelated, or unspecified donor source) has an average length of stay and average costs that are comparable to the average length of stay and average costs of all cases in MS–DRG 014. We also take this opportunity to note that, in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we do not consider the reported revenue codes. Rather, as stated previously, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We do this by evaluating the ICD–10–CM diagnosis and/or ICD–10–PCS procedure codes that identify the patient conditions, procedures, and the relevant MS–DRG(s) that are the subject of a request. Specifically, for this request, as noted above, we analyzed the cases reporting the ICD–10–PCS procedure codes that identify an allogeneic HCT procedure according to the donor source. We then evaluated patient care costs using average costs and average lengths of stay (based on the MedPAR data) and rely on the judgment of our clinical advisors to determine whether the patients are clinically distinct or similar to other patients represented in the MS–DRG. Because MS–DRG 014 is defined by patients who undergo an allogeneic HCT transplant procedure, our clinical advisors state they are all clinically similar in that regard. We also note that the ICD–10–PCS procedure codes that describe an allogeneic HCT procedure were revised effective October 1, 2016 to uniquely identify the donor source in response to a request and proposal that was discussed at the March 9–10, 2016 ICD–10 Coordination and Maintenance Committee meeting. We refer readers to the website at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html* for the committee meeting materials and discussion regarding this proposal.

In response to the requestor's statement that allogeneic related and allogeneic unrelated HCT cases are clinically different and have significantly different donor search and cell acquisition charges, our clinical advisors support maintaining the current structure for MS–DRG 014 because they believe that MS–DRG 014 appropriately classifies all patients who undergo an allogeneic HCT procedures and, therefore, it is clinically coherent. While the requestor stated that there are clinical differences in the related and unrelated HCT cases, they did not provide any specific examples of these clinical differences. With regard to the donor search and cell acquisition charges, the requestor noted that the unrelated donor cases are more expensive than the related donor cases because of the donor search process, which includes a registry search to identify the best donor source, extensive donor screenings, evaluation, and cell acquisition and transportation services for the patient. The requestor appeared to base that belief according to the donor source and average charges reported with revenue code 0815. As noted above, we use MedPAR data and do not consider the reported revenue codes in deciding whether to propose to make further modifications to the MS–DRGs. Based on our analysis of claims data for MS–DRG 014, our clinical advisors stated that the resources are similar for patients who undergo an allogeneic HCT procedure regardless of the donor source.

In reviewing this request, we also reviewed the instructions on billing for stem cell transplantation in Chapter 3 of the Medicare Claims Processing Manual and found that there appears to be inadvertent duplication under Section 90.3.1 and Section 90.3.3 of Chapter 3, as both sections provide instructions on Billing for Stem Cell Transplantation. Therefore, we are further reviewing the Medicare Claims Processing Manual to identify potential revisions to address this duplication. However, we also note that section 90.3.1 and section 90.3.3 provide different instruction regarding which revenue code should be reported. Section 90.3.1 instructs providers to report revenue code 0815 and Section 90.3.3 instructs providers to report revenue code 0819. We note that we issued instructions as a One-Time Notification, Pub. No. 100–04, Transmittal 3571, Change Request 9674, effective January 1, 2017, which instructs that the appropriate revenue code to report on claims for allogeneic stem cell acquisition/donor services is revenue code 0815. Accordingly, we also are considering additional revisions as needed to conform the instructions for reporting these codes in the Medicare Claims Processing Manual.

With regard to the requestor's recommendation that we create a new code edit through the inpatient MCE similar to the edit in the I/OCE which requires reporting of revenue code 0815 on the claim, we note that the MCE is not designed to include revenue codes for claims editing purposes. Rather, as stated in section II.F.16. of the preamble of this proposed rule, it is a software program that detects and reports errors in the coding of Medicare claims data. The coding of Medicare claims data refers to diagnosis and procedure coding, as well as demographic information.

For the reasons described above, we are not proposing to change the current structure of MS–DRG 014. We are not proposing to split MS–DRG 014 into two new MS–DRGs that assign cases according to whether the allogeneic donor source is related or unrelated, as the requestor suggested.

In addition, while conducting our analysis of cases reporting ICD–10–PCS

procedure codes for allogeneic HCT procedures that are assigned to MS–DRG 014, we noted that 8 procedure codes for autologous HCT procedures are currently included in MS–DRG 014, as shown in the following table. These codes are not properly assigned because MS–DRG 014 is defined by cases reporting allogenic HCT procedures.

ICD–10–PCS code	Code description
30230X0	Transfusion of autologous cord blood stem cells into peripheral vein, open approach.
30233X0	Transfusion of autologous cord blood stem cells into peripheral vein, percutaneous approach.
30240X0	Transfusion of autologous cord blood stem cells into central vein, open approach.
30243X0	Transfusion of autologous cord blood stem cells into central vein, percutaneous approach.
30250X0	Transfusion of autologous cord blood stem cells into peripheral artery, open approach.
30253X0	Transfusion of autologous cord blood stem cells into peripheral artery, percutaneous approach.
30260X0	Transfusion of autologous cord blood stem cells into central artery, open approach.
30263X0	Transfusion of autologous cord blood stem cells into central artery, percutaneous approach.

The 8 ICD–10–PCS procedure codes for autologous HCT procedures were inadvertently included in MS–DRG 014 as a result of efforts to replicate the ICD–9–CM MS–DRGs. Under the ICD–9–CM MS–DRGs, procedure code 41.06 (Cord blood stem cell transplant) was used to identify these procedures and was also assigned to MS–DRG 014. As shown in the ICD–9–CM code description, the reference to ''autologous'' is not included. However, because the ICD–10–PCS autologous HCT procedure codes were considered as plausible translations of the ICD–9–CM procedure code (41.06), they were inadvertently included in MS–DRG 014. We also note that, of these 8 procedure codes, there are 4 procedure codes that describe a transfusion via arterial access. As described in more detail below, because a transfusion procedure always uses venous access rather than arterial access, these codes are considered clinically invalid and were the subject of a proposal discussed at the March 5–6, 2019 ICD–10 Coordination and Maintenance Committee meeting to delete these codes effective October 1, 2019 (FY 2020).

The majority of ICD–10–PCS procedure codes specifying autologous HCT procedures are currently assigned to MS–DRGs 016 and 017 (Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy and Autologous Bone Marrow Transplant without CC/MCC, respectively). These codes are listed in the following table.

ICD–10–PCS code	Code description
30230AZ	Transfusion of embryonic stem cells into peripheral vein, open approach.
30230G0	Transfusion of autologous bone marrow into peripheral vein, open approach.
30230Y0	Transfusion of autologous hematopoietic stem cells into peripheral vein, open approach.
30233AZ	Transfusion of embryonic stem cells into peripheral vein, percutaneous approach.
30233G0	Transfusion of autologous bone marrow into peripheral vein, percutaneous approach.
30233Y0	Transfusion of autologous hematopoietic stem cells into peripheral vein, percutaneous approach.
30240AZ	Transfusion of embryonic stem cells into central vein, open approach.
30240G0	Transfusion of autologous bone marrow into central vein, open approach.
30240Y0	Transfusion of autologous hematopoietic stem cells into central vein, open approach.
30243AZ	Transfusion of embryonic stem cells into central vein, percutaneous approach.
30243G0	Transfusion of autologous bone marrow into central vein, percutaneous approach.
30243Y0	Transfusion of autologous hematopoietic stem cells into central vein, percutaneous approach.
30250G0	Transfusion of autologous bone marrow into peripheral artery, open approach.
30250Y0	Transfusion of autologous hematopoietic stem cells into peripheral artery, open approach.
30253G0	Transfusion of autologous bone marrow into peripheral artery, percutaneous approach.
30253Y0	Transfusion of autologous hematopoietic stem cells into peripheral artery, percutaneous approach.
30260G0	Transfusion of autologous bone marrow into central artery, open approach.
30260Y0	Transfusion of autologous hematopoietic stem cells into central artery, open approach.
30263G0	Transfusion of autologous bone marrow into central artery, percutaneous approach.
30263Y0	Transfusion of autologous hematopoietic stem cells into central artery, percutaneous approach.

While we believe, as indicated, that the cases reporting ICD–10–PCS procedure codes for autologous HCT procedures may be improperly assigned to MS–DRG 014, we also examined claims data for this subset of cases to determine the frequency with which they were reported and the relative resource use as compared with all cases assigned to MS–DRGs 016 and 017. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 014—Cases reporting autologous cord blood stem cell donor source	6	23.5	$38,319
MS–DRG 016—All cases	2,150	18	47,546
MS–DRG 017—All cases	104	11	33,540

For the subset of cases in MS–DRG 014 reporting ICD–10–PCS codes for autologous HCT procedures, there was a total of 6 cases with an average length of stay of 23.5 days and average costs of $38,319. The total number of cases reported in MS–DRG 016 was 2,150, with an average length of stay of 18 days and average costs of $47,546. The total number of cases reported in MS–DRG 017 was 104, with an average length of

stay of 11 days and average costs of $33,540.

The results of our analysis indicate that the frequency with which these autologous HCT procedure codes was reported in MS–DRG 014 is low and that average costs of cases reporting autologous HCT procedures assigned to MS–DRG 014 are more aligned with the average costs of cases assigned to MS–DRGs 016 and 017, with the average costs being lower than the average costs for all cases assigned to MS–DRG 016 and higher than the average costs for all cases assigned to MS–DRG 017. Our clinical advisors also indicated that the procedure codes for autologous HCT procedures are more clinically aligned with cases that are assigned to MS–DRGs 016 and 017 that are comprised of autologous HCT procedures. Therefore, we are proposing to reassign the following 4 procedure codes for HCT procedures specifying autologous cord blood stem cell as the donor source via venous access to MS–DRGs 016 and 017 for FY 2020.

ICD–10–PCS code	Code description
30230X0	Transfusion of autologous cord blood stem cells into peripheral vein, open approach.
30233X0	Transfusion of autologous cord blood stem cells into peripheral vein, percutaneous approach.
30240X0	Transfusion of autologous cord blood stem cells into central vein, open approach.
30243X0	Transfusion of autologous cord blood stem cells into central vein, percutaneous approach.

As discussed earlier in this section, the 4 procedure codes for HCT procedures that describe an autologous cord blood stem cell transfusion via arterial access currently assigned to MS–DRG 014, as listed previously, are considered clinically invalid. These procedure codes were discussed at the March 5–6, 2019 ICD–10 Coordination and Maintenance Committee meeting, along with additional procedure codes that are also considered clinically invalid, as described in the section below.

During our analysis of procedure codes that describe a HCT procedure, we identified 128 clinically invalid codes from the transfusion table (table 302) in the ICD–10–PCS classification identifying a transfusion using arterial access, as listed in Table 6P.1a. associated with this proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). As shown in Table 6P.1a., these 128 procedure codes describe transfusion procedures with body system/region values ''5'' Peripheral Artery and ''6'' Central Artery. Because a transfusion procedure always uses venous access rather than arterial access, these codes are considered clinically invalid and were proposed for deletion at the March 5–6, 2019 ICD–10 Coordination and Maintenance Committee meeting. We refer the reader to the website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html* for the Committee meeting materials regarding this proposal.

We examined claims data from the September 2018 update of the FY 2018 MedPAR file for MS–DRGs 014, 016, and 017 to determine if there were any cases that reported one of the 128 clinically invalid codes from the transfusion table in the ICD–10–PCS classification identifying a transfusion using arterial access, and as listed in Table 6P.1a. associated with this proposed rule. Our clinical advisors agree that because a transfusion procedure always uses venous access rather than arterial access, these codes are considered invalid. Because these procedure codes describe clinically invalid procedures, we would not expect these codes to be reported in any claims data. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 014, 016, and 017—All cases	3,108	20.4	$59,140
MS–DRGs 014, 016, and 017—Cases with invalid transfusion codes	31	19.6	52,912

As shown in this table, we found a total of 3,108 cases across MS–DRGs 014, 016, and 017 with an average length of stay of 20.4 days and average costs of $59,140. We found a total of 31 cases (0.9 percent) reporting a procedure code for an invalid transfusion procedure, identifying the body system/region value ''5'' Peripheral Artery or ''6'' Central Artery, with an average length of stay of 19.6 days and average costs of $52,912. The results of the data analysis demonstrate that these invalid transfusion procedures represent approximately 1 percent of all discharges across MS–DRGs 014, 016, and 017. To summarize, we are proposing to: (1) Reassign the four ICD–10–PCS codes for HCT procedures specifying autologous cord blood stem cell as the donor source from MS–DRG 014 to MS–DRGs 016 and 017 (procedure codes 30230X0, 30233X0, 30240X0, 30243X0); and (2) delete the 128 clinically invalid codes from the transfusion table in the ICD–10–PCS Classification describing a transfusion using arterial access that were discussed at the March 5–6, 2019 ICD–10 Coordination and Maintenance Committee meeting and are listed in Table 6P.1a associated with this proposed rule. As discussed previously, we are not proposing to split MS–DRG 014 into the two requested new MS DRGs that would assign cases according to whether the allogeneic donor source is related or unrelated.

c. Chimeric Antigen Receptor (CAR) T-Cell Therapies

We received a request to create a new MS–DRG for procedures involving CAR T-cell therapies. The requestor stated that creation of a new MS–DRG would improve payment for CAR T-cell therapies in the inpatient setting. According to the requestor, while cases involving CAR T-cell therapy may now be eligible for new technology add-on payments and outlier payments, there continue to be significant financial losses by providers. The requestor also suggested that CMS modify its existing payment mechanisms to use a CCR of 1.0 for charges associated with CAR T-cell therapy.

In addition, the requestor included technical and operational suggestions related to CAR T-cell therapy, such as

the development of unique CAR T-cell therapy revenue and cost centers for billing and cost reporting purposes. We will consider these technical and operational suggestions in the development of future billing and cost reporting guidelines and instructions.

Currently, procedures involving CAR T-cell therapies are identified with ICD–10–PCS procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3), which became effective October 1, 2017. In the FY 2019 IPPS/LTCH PPS final rule, we finalized our proposal to assign cases reporting these ICD–10–PCS procedure codes to Pre-MDC MS–DRG 016 for FY 2019 and to revise the title of this MS–DRG to ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy''. We refer readers to section II.F.2.d. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a complete discussion of these final policies (83 FR 41172 through 41174).

As stated earlier, the current procedure codes for CAR T-cell therapies both became effective October 1, 2017. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41172 through 41174), we indicated we should collect more comprehensive clinical and cost data before considering assignment of a new MS–DRG to these therapies. While the September 2018 update of the FY 2018 MedPAR data file does contain some claims that include those procedure codes that identify CAR T-cell therapies, the number of cases is limited, and the submitted costs vary widely due to differences in provider billing and charging practices for this therapy. Therefore, while these claims could potentially be used to create relative weights for a new MS–DRG, we do not have the comprehensive clinical and cost data that we generally believe are needed to do so. Furthermore, given the relative newness of CAR T-cell therapy and our proposal to continue new technology add-on payments for FY 2020 for the two CAR T-cell therapies that currently have FDA approval (KYMRIAH™ and YESCARTA™), as discussed in section II.G.4.d. of the preamble of this proposed rule, at this time we believe it may be premature to consider creation of a new MS–DRG specifically for cases involving CAR T-cell therapy for FY 2020.

Therefore, we are proposing not to modify the current MS–DRG assignment for cases reporting CAR T-cell therapies for FY 2020. As noted earlier, cases reporting ICD–10–PCS codes XW033C3 and XW043C3 would continue to be eligible to receive new technology add-on payments for discharges occurring in FY 2020 if our proposal to continue such payments is finalized. Currently, we expect that, in future years, we would have additional data that exhibit more stability and greater consistency in charging and billing practices that could be used to evaluate the potential creation of a new MS–DRG specifically for cases involving CAR T-cell therapies.

Alternatively, notwithstanding our concerns regarding the claims data, and the concerns discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41172 to 41174), we are seeking public comments on payment alternatives for CAR T-cell therapies, including payment under any potential new MS–DRG. We also are inviting public comments on how these payment alternatives would affect access to care, as well as how they affect incentives to encourage lower drug prices, which is a high priority for this Administration. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41172 through 41174), we are considering approaches and authorities to encourage value-based care and lower drug prices. We are soliciting public comments on how the effective dates of any potential payment methodology alternatives, if any were to be adopted, may intersect and affect future participation in any such alternative approaches.

As part of our solicitation of public comment on the potential creation of a new MS–DRG for CAR T-cell therapy procedures, we are also seeking comment on the most appropriate way to develop the relative weight if we were to finalize the creation of a new MS–DRG. While the data are limited, it may be operationally possible to create a relative weight by dividing the average costs of cases that include the CAR T-cell procedures by the average costs of all cases, consistent with our current methodology for setting the relative weights for FY 2020 and using the same applicable data sources used for other MS–DRGs (for FY 2020, the FY 2018 MedPAR data and FY 2016 HCRIS data). We are seeking public comments on whether this is the most accurate method for determining the relative weight, given the current variation in the claims data for these procedures, and also on how to address the significant number of cases involving clinical trials. While we do not typically exclude cases in clinical trials when developing the relative weights, in this case, the absence of the drug costs on claims for cases involving clinical trial claims could have a significant impact on the relative weight. It is unclear whether a relative weight calculated using cases for which hospitals do and do not incur drug costs would accurately reflect the resource costs of caring for patients who are not involved in clinical trials. A different approach might be to develop a relative weight using an appropriate portion of the average sales price (ASP) for these drugs as an alternative way to reflect the costs involved in treating patients receiving CAR T-cell therapies. We are requesting public comments on these approaches or other approaches for setting the relative weight if we were to finalize a new MS–DRG. We note that any such new MS–DRG would be established in a budget neutral manner, consistent with section 1886(d)(4)(C)(iii) of the Act, which specifies that the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected.

Another potential consideration if we were to create a new MS–DRG is the extent to which it would be appropriate to geographically adjust the payment under any such new MS–DRG. Under the methodology for determining the Federal payment rate for operating costs under the IPPS, the labor-related proportion of the national standardized amounts is adjusted by the wage index to reflect the relative differences in labor costs among geographic areas. The IPPS Federal payment rate for operating costs is calculated as the MS–DRG relative weight × [(labor-related applicable standardized amount × applicable wage index) + (nonlabor-related applicable standardized amount × cost-of-living adjustment)]. Given our understanding that the costs for CAR T-cell therapy drugs do not vary among geographic areas, and given that costs for CAR T-cell therapy would likely be an extremely high portion of the costs for the MS–DRG, we are seeking public comments on whether we should not geographically adjust the payment for cases assigned to any potential new MS–DRG for CAR T-cell therapy procedures. We also are seeking public comments on whether to instead apply the geographic adjustment to a lower proportion of payments under any potential new MS–DRG and, if so, how that lower proportion should be determined. We note that while the prices of other drugs may also not vary significantly among geographic areas, generally speaking, those other drugs would not have estimated costs as high

as those of CAR T-cell therapies, nor would they represent as significant a percentage of the average costs for the case. We are seeking public comments on the use of our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act (or other relevant authorities) to implement any such potential changes.

Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved graduate medical education (GME) program receive an additional payment for a Medicare discharge to reflect the higher patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at 42 CFR 412.105. The formula is traditionally described in terms of a certain percentage increase in payment for every 10-percent increase in the resident-to-bed ratio. For some hospitals, this percentage increase can exceed an additional 25 percent or more of the otherwise applicable payment. Some hospitals, sometimes the same hospitals, can also receive a large percentage increase in payments due to the Medicare disproportionate hospital (DSH) adjustment provision under section 1886(d)(5)(F) of the Act. The regulations regarding the calculation of the additional DSH payment are located at 42 CFR 412.106.

Given that the payment for cases assigned to a new MS–DRG for CAR T-cell therapy could significantly exceed the historical payment for any existing MS–DRG, these percentage add-on payments could arguably result in unreasonably high additional payments for CAR T-cell therapy cases unrelated in any significant empirical way to the costs of the hospital in providing care. For example, consider a teaching hospital that has an IME adjustment factor of 0.25, and a DSH adjustment factor of 0.10. If we were to create a new MS–DRG for CAR T-cell therapy procedures that resulted in an average IPPS Federal payment rate for operating costs of $400,000, under the current payment mechanism, the hospital would receive an IME payment of $100,000 ($400,000 × 0.25) and a DSH payment of $40,000 ($400,000 × 0.10), such that the total IPPS Federal payment rate for operating costs including IME and DSH payments would be $540,000 ($400,000 + $100,000 + $40,000). We are seeking public comments on whether the IME and DSH payments should not be made for cases assigned to any new MS–DRG for CAR T-cell therapy. We also are seeking public comments on whether we should instead reduce the applicable percentages used to determine these add-ons and, if so, how those lower percentages should be determined. We are seeking public comments on the use of our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act (or other relevant authorities) to implement any potential changes.

As further discussed section II.G.7. of the preamble to this proposed rule, we are also requesting public comment on other payment alternatives for these cases, including eliminating the use of the CCR in calculating the new technology add-on payment for KYMRIAH® and YESCARTA® by making a uniform add-on payment that equals the proposed maximum add-on payment, that is, 65 percent of the cost of the technology (in accordance with the proposed increase in the calculation of the maximum new technology add-on payment amount), which in this instance would be $242,450; and/or using a higher percentage than the proposed 65 percent to calculate the maximum new technology add-on payment amount.

We are also requesting public comments on whether, in light of the additional experience with billing and payment for cases involving CAR T-cell therapies to Medicare patients, we should consider utilizing a specific CCR for ICD–10–PCS procedure codes used to report the performance of procedures involving the use of CAR T-cell therapies; for example, a CCR of 1.0, when determining outlier payments, when determining the new technology add-on payments, and when determining payments to IPPS-excluded cancer hospitals for CAR T-cell therapies.

We note that we also considered this payment alternative for FY 2019, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41172 through 41174). We indicated in that rulemaking that such a payment alternative might use a CCR of 1.0 for charges associated with ICD–10–PCS procedure codes XW033C3 and XW043C3, given that many public inquirers believed that hospitals would be unlikely to set charges different from the costs for KYMRIAH® and YESCARTA® CAR T-cell therapies. We also indicated such a change would result in a higher outlier payment, higher new technology add-on payment, or the determination of higher costs for IPPS-excluded cancer hospital cases. For example, and as described in the FY 2019 IPPS LTCH PPS final rule (83 FR 41773), if a hospital charged $400,000 for the procedure described by ICD–10–PCS procedure code XW033C3, the application of a hypothetical CCR of 0.25 results in a cost of $100,000 (= $400,000 * 0.25) while the application of a hypothetical CCR of 1.00 results in a cost of $400,000 (= $400,000 * 1.0).

3. MDC 1 (Diseases and Disorders of the Nervous System): Carotid Artery Stent Procedures

The logic for case assignment to MS–DRGs 034, 035, and 036 (Carotid Artery Stent Procedures with MCC, with CC, and without CC/MCC, respectively) as displayed in the ICD–10 MS–DRG Version 36 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html*) is comprised of two lists of logic that include procedure codes for operating room (O.R.) procedures involving dilation of a carotid artery (common, internal or external) with intraluminal device(s). The first list of logic is entitled ''Operating Room Procedures'' and the second list of logic is entitled ''Operating Room Procedures with Operating Room Procedures''. We identified 46 ICD–10–PCS procedure codes in the second logic list that do not describe dilation of a carotid artery with an intraluminal device. Of these 46 procedure codes, we identified 24 codes describing dilation of a carotid artery without an intraluminal device; 8 codes describing dilation of the vertebral artery; and 14 codes describing dilation of a vein (jugular, vertebral and face), as shown in the following table.

ICD–10 PCS Codes That Involve Dilation of a Neck Artery or Vein With and Without an Intraluminal Device

ICD–10–PCS code	Code description
037H3Z6	Dilation of right common carotid artery, bifurcation, percutaneous approach.
037H3ZZ	Dilation of right common carotid artery, percutaneous approach.

ICD–10 PCS CODES THAT INVOLVE DILATION OF A NECK ARTERY OR VEIN WITH AND WITHOUT AN INTRALUMINAL DEVICE—Continued

ICD–10–PCS code	Code description
037H4Z6	Dilation of right common carotid artery, bifurcation, percutaneous endoscopic approach.
037H4ZZ	Dilation of right common carotid artery, percutaneous endoscopic approach.
037J3Z6	Dilation of left common carotid artery, bifurcation, percutaneous approach.
037J3ZZ	Dilation of left common carotid artery, percutaneous approach.
037J4Z6	Dilation of left common carotid artery, bifurcation, percutaneous endoscopic approach.
037J4ZZ	Dilation of left common carotid artery, percutaneous endoscopic approach.
037K3Z6	Dilation of right internal carotid artery, bifurcation, percutaneous approach.
037K3ZZ	Dilation of right internal carotid artery, percutaneous approach.
037K4Z6	Dilation of right internal carotid artery, bifurcation, percutaneous endoscopic approach.
037K4ZZ	Dilation of right internal carotid artery, percutaneous endoscopic approach.
037L3Z6	Dilation of left internal carotid artery, bifurcation, percutaneous approach.
037L3ZZ	Dilation of left internal carotid artery, percutaneous approach.
037L4Z6	Dilation of left internal carotid artery, bifurcation, percutaneous endoscopic approach.
037L4ZZ	Dilation of left internal carotid artery, percutaneous endoscopic approach.
037M3Z6	Dilation of right external carotid artery, bifurcation, percutaneous approach.
037M3ZZ	Dilation of right external carotid artery, percutaneous approach.
037M4Z6	Dilation of right external carotid artery, bifurcation, percutaneous endoscopic approach.
037M4ZZ	Dilation of right external carotid artery, percutaneous endoscopic approach.
037N3Z6	Dilation of left external carotid artery, bifurcation, percutaneous approach.
037N3ZZ	Dilation of left external carotid artery, percutaneous approach.
037N4Z6	Dilation of left external carotid artery, bifurcation, percutaneous endoscopic approach.
037N4ZZ	Dilation of left external carotid artery, percutaneous endoscopic approach.
037P3Z6	Dilation of right vertebral artery, bifurcation, percutaneous approach.
037P3ZZ	Dilation of right vertebral artery, percutaneous approach.
037P4Z6	Dilation of right vertebral artery, bifurcation, percutaneous endoscopic approach.
037P4ZZ	Dilation of right vertebral artery, percutaneous endoscopic approach.
037Q3Z6	Dilation of left vertebral artery, bifurcation, percutaneous approach.
037Q3ZZ	Dilation of left vertebral artery, percutaneous approach.
037Q4Z6	Dilation of left vertebral artery, bifurcation, percutaneous endoscopic approach.
037Q4ZZ	Dilation of left vertebral artery, percutaneous endoscopic approach.
057M3DZ	Dilation of right internal jugular vein with intraluminal device, percutaneous approach.
057M4DZ	Dilation of right internal jugular vein with intraluminal device, percutaneous endoscopic approach.
057N3DZ	Dilation of left internal jugular vein with intraluminal device, percutaneous approach.
057N4DZ	Dilation of left internal jugular vein with intraluminal device, percutaneous endoscopic approach.
057P3DZ	Dilation of right external jugular vein with intraluminal device, percutaneous approach.
057P4DZ	Dilation of right external jugular vein with intraluminal device, percutaneous endoscopic approach.
057Q3DZ	Dilation of left external jugular vein with intraluminal device, percutaneous approach.
057Q4DZ	Dilation of left external jugular vein with intraluminal device, percutaneous endoscopic approach.
057R3DZ	Dilation of left vertebral vein with intraluminal device, percutaneous approach.
057R4DZ	Dilation of right vertebral vein with intraluminal device, percutaneous endoscopic approach.
057S3DZ	Dilation of left vertebral vein with intraluminal device, percutaneous approach.
057S4DZ	Dilation of left vertebral vein with intraluminal device, percutaneous endoscopic approach.
057T3DZ	Dilation of right face vein with intraluminal device, percutaneous approach.
057T4DZ	Dilation of right face vein with intraluminal device, percutaneous endoscopic approach.

We examined claims data from the September 2018 update of the FY 2018 MedPAR file for MS–DRGs 034, 035, and 036 and identified cases reporting any one of the 46 ICD–10–PCS procedure codes listed in the tables above. Our findings are shown in the following table.

MS–DRGS FOR CAROTID ARTERY STENT PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 034—All cases	863	6.8	$27,600
MS–DRG 034—Cases with procedure code other than dilation of a carotid artery with an intraluminal device	15	8.8	36,596
MS–DRG 035—All cases	2,369	3	16,731
MS–DRG 035—Cases with procedure code other than dilation of a carotid artery with an intraluminal device	52	3.5	17,815
MS–DRG 036—All cases	3,481	1.4	12,637
MS–DRG 036—Cases with procedure code other than dilation of a carotid artery with an intraluminal device	67	1.4	12,621

As shown in the table above, we found a total of 863 cases with an average length of stay of 6.8 days and average costs of $27,600 in MS–DRG 034. There were 15 cases reporting at least one of the 46 procedure codes that

do not describe dilation of the carotid artery with an intraluminal device in MS–DRG 034 with an average length of stay of 8.8 days and average costs of $36,596. For MS–DRG 035, we found a total of 2,369 cases with an average length of stay of 3 days and average costs of $16,731. There were 52 cases reporting at least one of the 46 procedure codes that do not describe dilation of the carotid artery with an intraluminal device in MS–DRG 035 with an average length of stay of 3.5 days and average costs of $17,815. For MS–DRG 036, we found a total of 3,481 cases with an average length of stay of 1.4 days and average costs of $12,637. There were 67 cases reporting at least one of the 46 procedure codes that do not describe dilation of the carotid artery with an intraluminal device in MS–DRG 036 with an average length of stay of 1.4 days and average costs of $12,621.

Our clinical advisors stated that MS–DRGs 034, 035, and 036 are defined to include only those procedure codes that describe procedures that involve dilation of a carotid artery with an intraluminal device. Therefore, we are proposing to remove the procedure codes listed in the table above from MS–DRGs 034, 035, and 036 that describe procedures which (1) do not include an intraluminal device; (2) describe procedures performed on arteries other than a carotid; and (3) describe procedures performed on a vein.

The 46 ICD–10–PCS procedure codes listed in the table above are also assigned to MS–DRGs 037, 038, and 039 (Extracranial Procedures with MCC, with CC, and without CC/MCC, respectively). Therefore, we also examined claims data from the September 2018 update of the FY 2018 MedPAR file for MS–DRGs 037, 038, and 039. Our findings are shown in the following table.

MS–DRGS FOR EXTRACRANIAL PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 037—All cases	3,612	7.1	$23,703
MS–DRG 038—All cases	11,406	3.1	12,480
MS–DRG 039—All cases	22,938	1.5	8,400

We found a total of 3,612 cases in MS–DRG 037 with an average length of stay of 7.1 days and average costs of $23,703. We found a total of 11,406 cases in MS–DRG 038 with an average length of stay of 3.1 days and average costs of $12,480. We found a total of 22,938 cases in MS–DRG 039 with an average length of stay of 1.5 days and average costs of $8,400.

During our review of claims data for MS–DRGs 037, 038, and 039, we also discovered 96 ICD–10–PCS procedure codes describing dilation of a carotid artery with an intraluminal device that were inadvertently included as a result of efforts to replicate the ICD–9 based MS–DRGs. These procedure codes are also included in the logic for MS–DRGs 034, 035, and 036. Under ICD–9–CM, procedure codes 00.61 (Percutaneous angioplasty of extracranial vessel(s)) and 00.63 (Percutaneous insertion of carotid artery stent(s)) are both required to be reported on a claim to identify that a carotid artery stent procedure was performed and for assignment of the case to MS–DRGs 034, 035, and 036. Procedure code 00.61 is designated as an O.R. procedure, while procedure code 00.63 is designated as a non-O.R. procedure. Under ICD–10–PCS, a carotid artery stent procedure is described by one unique code that includes both clinical concepts of the angioplasty (dilation) and the insertion of the stent (intraluminal device). This ''combination code'' under ICD–10–PCS is designated as an O.R. procedure. Under ICD–9–CM, procedure code 00.61 reported in the absence of procedure code 00.63 results in assignment to MS–DRGs 037, 038, and 039 according to the MS–DRG logic because procedure code 00.61 has an inclusion term for vertebral vessels, as well as for the carotid vessels. Therefore, when all of the comparable translations of procedure code 00.61 as an O.R. procedure were replicated from the ICD–9 based MS–DRGs to the ICD–10 based MS–DRGs, this replication inadvertently results in the assignment of ICD–10–PCS procedure codes that identify and describe a carotid artery stent procedure to MS–DRGs 037, 038, and 039. Therefore, we are proposing to remove the 96 ICD–10–PCS procedure codes describing dilation of a carotid artery with an intraluminal device from MS–DRGs 037, 038, and 039.

We also found 6 procedure codes describing dilation of a carotid artery with an intraluminal device in MS–DRGs 037, 038, and 039 that are not currently assigned to MS–DRGs 034, 035, and 036. Our clinical advisors recommended that these 6 procedure codes be reassigned from MS–DRGs 037, 038, and 039 to MS–DRGs 034, 035, and 036 because the 6 procedure codes are consistent with the other procedures describing dilation of a carotid artery with an intraluminal device that are currently assigned to MS–DRGs 034, 035, and 036. We refer readers to Table 6P.1b. associated with this proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for the complete list of procedure codes that we are proposing to remove from MS–DRGs 037, 038, and 039.

We also note that, as discussed in section II.F.14.f. of the preamble of this proposed rule, we are deleting a number of codes that include the ICD–10–PCS qualifier term ''bifurcation'' as the result of the finalized proposal discussed at the September 11–12, 2018 ICD–10 Coordination and Maintenance Committee meeting. We refer readers to the website at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html* for the committee meeting materials and discussion regarding this proposal. We note that, of the 96 procedure codes that we are proposing to remove from the logic for MS–DRGs 037, 038, and 039, there are 48 procedure codes that include the qualifier term ''bifurcation''. Therefore, these 48 procedure codes will be deleted effective October 1, 2019. The 48 remaining valid procedure codes that do not include the term ''bifurcation'' that we are proposing to remove from MS–DRGs 037, 038, and 039 will continue to be assigned to MS–DRGs 034, 035, and 036.

Lastly, if the applicable proposed MS–DRG changes are finalized, we would make a conforming change to the ICD–10 MS–DRG Version 37 Definitions Manual for FY 2020 by combining all the procedure codes identifying a carotid artery stent procedure within MS–DRGs 034, 035, and 036 into one list entitled ''Operating Room Procedures'' to better reflect the

definition of these MS–DRGs based on the discussion and proposals described above.

4. MDC 4 (Diseases and Disorders of the Respiratory System): Pulmonary Embolism

We received a request to reassign three ICD–10–CM diagnosis codes for pulmonary embolism with acute cor pulmonale from MS–DRG 176 (Pulmonary Embolism without MCC) to the higher severity level MS–DRG 175 (Pulmonary Embolism with MCC). The three diagnosis codes are identified in the following table.

ICD–10–CM code	Code description
I26.01	Septic pulmonary embolism with acute cor pulmonale.
I26.02	Saddle embolus of pulmonary artery with acute cor pulmonale.
I26.09	Other pulmonary embolism with acute cor pulmonale.

The requestor noted that, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41231 through 41234), we finalized the proposal to remove the special logic in the GROUPER for processing claims containing a code on the Principal Diagnosis Is Its Own CC or MCC Lists and deleted the relevant tables from the ICD–10 MS–DRG Definitions Manual Version 36, effective October 1, 2018. As a result of this change, cases reporting any one of the three ICD–10–CM diagnosis codes describing a pulmonary embolism with acute cor pulmonale were reassigned from MS–DRG 175 to MS–DRG 176, absent a secondary diagnosis code to trigger assignment to MS–DRG 175. The requestor stated that this change in the MS–DRG assignment for these cases resulted in a reduction in payment for cases involving pulmonary embolism with acute cor pulmonale and that the FY 2019 payment rate for MS–DRG 176 does not appropriately account for the costs and resource utilization associated with these cases because the subset of patients with pulmonary embolism with acute cor pulmonale often represents a more severe set of patients with pulmonary embolism.

The logic for case assignment to MS–DRGs 175 and 176 is displayed in the ICD–10 MS–DRG Version 36 Definitions Manual, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html*.

We analyzed claims data from the September 2018 update of the FY 2018 MedPAR file for MS–DRGs 175 and 176 to identify cases reporting diagnosis codes describing pulmonary embolism with acute cor pulmonale as listed above (ICD–10–CM diagnosis codes I26.01, I26.02 or I26.09) as the principal diagnosis or as a secondary diagnosis. Our findings are shown in the following table.

MS–DRGs FOR PULMONARY EMBOLISM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 175—All cases	24,389	5.2	$10,294
MS–DRG 175—Cases with pulmonary embolism with acute cor pulmonale	2,326	5.7	13,034
MS–DRG 176—All cases	30,215	3.3	6,356
MS–DRG 176—Cases with pulmonary embolism with acute cor pulmonale	1,821	3.9	9,630

As shown in the table, for MS–DRG 175, there was a total of 24,389 cases with an average length of stay of 5.2 days and average costs of $10,294. Of these 24,389 cases, there were 2,326 cases reporting pulmonary embolism with acute cor pulmonale, with an average length of stay 5.7 days and average costs of $13,034. For MS–DRG 176, there was a total of 30,215 cases with an average length of stay of 3.3 days and average costs of $6,356. Of these 30,215 cases, there were 1,821 cases reporting pulmonary embolism with acute cor pulmonale with an average length of stay of 3.9 days and average costs of $9,630.

As stated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41231 through 41234), available ICD–10 data can now be used to evaluate other indicators of resource utilization and, as shown by our claims analysis, the data indicate that the average costs of cases reporting pulmonary embolism or saddle embolus with acute cor pulmonale ($9,630) in MS–DRG 176 are closer to the average costs for all pulmonary embolism cases in MS–DRG 175 ($10,294) as compared to the average costs for all cases in MS–DRG 176 ($6,356). Our clinical advisors also agree that this subset of patients with acute cor pulmonale often represents a more severe set of patients and that these cases are more appropriately assigned to the higher severity level ''with MCC'' MS–DRG. Therefore, we are proposing to reassign cases reporting diagnosis code I26.01, I26.02, or I26.09 to the higher severity level MS–DRG 175 and to revise the title for MS–DRG 175 to ''Pulmonary Embolism with MCC or Acute Cor Pulmonale'' to more accurately reflect the diagnoses assigned there.

5. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Transcatheter Mitral Valve Repair With Implant

As we did for the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28008 through 28010) and for the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24985 through 24989), for FY 2020, we received a request to modify the MS–DRG assignment for transcatheter mitral valve repair (TMVR) with implant procedures. ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) identifies and describes this procedure. This request also included the suggestion that CMS give consideration to reclassifying other endovascular cardiac valve repair procedures. Specifically, the requestor recommended that cases reporting procedure codes describing an endovascular cardiac valve repair with implant be reassigned to MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with and without MCC, respectively) and that the MS–DRG titles be revised to Endovascular Cardiac Valve Interventions with Implant with and without MCC, respectively. We refer readers to detailed discussions of

the MitraClip® System (hereafter referred to as MitraClip®) for transcatheter mitral valve repair in previous rulemakings, including the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25822) and final rule (76 FR 51528 through 51529), the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27902 through 27903) and final rule (77 FR 53308 through 53310), the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28008 through 28010) and final rule (79 FR 49889 through 49892), the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24356 through 24359) and final rule (80 FR 49363 through 49367), and the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24985 through 24989) and final rule (81 FR 56809 through 56813), in response to requests for MS–DRG reclassification, as well as the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27547 through 27552), under the new technology add-on payment policy. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50575), we were unable to consider further the application for a new technology add-on payment for MitraClip® because the technology had not received FDA approval by the July 1, 2013 deadline.

In the FY 2015 IPPS/LTCH PPS final rule, we finalized our proposal to not create a new MS–DRG or to reassign cases reporting ICD–9–CM procedure code 35.97 that described procedures involving the MitraClip® to another MS–DRG (79 FR 49889 through 49892). Under a new application, the request for new technology add-on payments for the MitraClip® System was approved for FY 2015 (79 FR 49941 through 49946). The new technology add-on payment for MitraClip® was subsequently discontinued effective FY 2017.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49371), we finalized a modification to the MS–DRGs to which procedures involving the MitraClip® were assigned. For the ICD–10 based MS–DRGs to fully replicate the ICD–9–CM based MS–DRGs, ICD–10–PCS code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach), which identifies the MitraClip® technology and is the ICD–10–PCS code translation for ICD–9–CM procedure code 35.97 (Percutaneous mitral valve repair with implant), was assigned to new MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with MCC and without MCC, respectively) and continued to be assigned to MS–DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively).

In the FY 2017 IPPS/LTCH PPS proposed and final rules, we also discussed our analysis of MS–DRGs 228, 229, and 230 (Other Cardiothoracic Procedures with MCC, with CC, and without CC/MCC, respectively) with regard to the possible reassignment of cases reporting ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach). We finalized our proposal to collapse these MS–DRGs (228, 229, and 230) from three severity levels to two severity levels by deleting MS–DRG 230 and revising the structure of MS–DRG 229. We also finalized our proposal to reassign ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) from MS–DRGs 273 and 274 to MS–DRG 228 and revised MS–DRG 229 (81 FR 56813).

According to the requestor, there are substantial clinical and resource differences between the transcatheter mitral valve repair (TMVR) procedure and other procedures currently grouping to MS–DRGs 228 and 229. The requestor noted that, currently, ICD–10–PCS procedure code 02UG3JZ is the only endovascular valve intervention with implant procedure that maps to MS–DRGs 228 and 229. The requestor also noted that other ICD–10–PCS procedure codes describing procedures for endovascular (transcatheter) cardiac valve repair with implant map to MS–DRGs 273 and 274 or to MS–DRGs 216, 217, 218, 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures with and without Cardiac Catheterization with MCC, with CC and without CC/MCC, respectively). The requestor further noted that all ICD–10–PCS procedure codes for endovascular cardiac valve replacement procedures map to MS–DRGs 266 (Endovascular Cardiac Valve Replacement with MCC) and 267 (Endovascular Cardiac Valve Replacement without MCC).

The ICD–10–PCS procedure codes describing a transcatheter cardiac valve repair procedure with an implant are listed in the following table.

ICD–10–PCS code	Description
02UF37J	Supplement aortic valve created from truncal valve with autologous tissue substitute, percutaneous approach.
02UF37Z	Supplement aortic valve with autologous tissue substitute, percutaneous approach.
02UF38J	Supplement aortic valve created from truncal valve with zooplastic tissue, percutaneous approach.
02UF38Z	Supplement aortic valve with zooplastic tissue, percutaneous approach.
02UF3JJ	Supplement aortic valve created from truncal valve with synthetic substitute, percutaneous approach.
02UF3JZ	Supplement aortic valve with synthetic substitute, percutaneous approach.
02UF3KJ	Supplement aortic valve created from truncal valve with nonautologous tissue substitute, percutaneous approach.
02UF3KZ	Supplement aortic valve with nonautologous tissue substitute, percutaneous approach.
02UG37E	Supplement mitral valve created from left atrioventricular valve with autologous tissue substitute, percutaneous approach.
02UG37Z	Supplement mitral valve with autologous tissue substitute, percutaneous approach.
02UG38E	Supplement mitral valve created from left atrioventricular valve with zooplastic tissue, percutaneous approach.
02UG38Z	Supplement mitral valve with zooplastic tissue, percutaneous approach.
02UG3KE	Supplement mitral valve created from left atrioventricular valve with nonautologous tissue substitute, percutaneous approach.
02UG3KZ	Supplement mitral valve with nonautologous tissue substitute, percutaneous approach.
02UG3JE	Supplement mitral valve created from left atrioventricular valve with synthetic substitute, percutaneous approach.
02UG3JZ	Supplement mitral valve with synthetic substitute, percutaneous approach.
02UH37Z	Supplement pulmonary valve with autologous tissue substitute, percutaneous approach.
02UH38Z	Supplement pulmonary valve with zooplastic tissue, percutaneous approach.
02UH3JZ	Supplement pulmonary valve with synthetic substitute, percutaneous approach.
02UH3KZ	Supplement pulmonary valve with nonautologous tissue substitute, percutaneous approach.
02UJ37G	Supplement tricuspid valve created from right atrioventricular valve with autologous tissue substitute, percutaneous approach.
02UJ37Z	Supplement tricuspid valve with autologous tissue substitute, percutaneous approach.
02UJ38G	Supplement tricuspid valve created from right atrioventricular valve with zooplastic tissue, percutaneous approach.
02UJ38Z	Supplement tricuspid valve with zooplastic tissue, percutaneous approach.
02UJ3JG	Supplement tricuspid valve created from right atrioventricular valve with synthetic substitute, percutaneous approach.
02UJ3JZ	Supplement tricuspid valve with synthetic substitute, percutaneous approach.

ICD–10–PCS code	Description
02UJ3KG	Supplement tricuspid valve created from right atrioventricular valve with nonautologous tissue substitute, percutaneous approach.
02UJ3KZ	Supplement tricuspid valve with nonautologous tissue substitute, percutaneous approach.

The ICD–10–PCS procedure codes describing a transcatheter cardiac valve replacement procedure are listed in the following table.

ICD–10–PCS code	Description
02RF37H	Replacement of aortic valve with autologous tissue substitute, transapical, percutaneous approach.
02RF37Z	Replacement of aortic valve with autologous tissue substitute, percutaneous approach.
02RF38H	Replacement of aortic valve with zooplastic tissue, transapical, percutaneous approach.
02RF38Z	Replacement of aortic valve with zooplastic tissue, percutaneous approach.
02RF3JH	Replacement of aortic valve with synthetic substitute, transapical, percutaneous approach.
02RF3JZ	Replacement of aortic valve with synthetic substitute, percutaneous approach.
02RF3KH	Replacement of aortic valve with nonautologous tissue substitute, transapical, percutaneous approach.
02RF3KZ	Replacement of aortic valve with nonautologous tissue substitute, percutaneous approach.
02RG37H	Replacement of mitral valve with autologous tissue substitute, transapical, percutaneous approach.
02RG37Z	Replacement of mitral valve with autologous tissue substitute, percutaneous approach.
02RG38H	Replacement of mitral valve with zooplastic tissue, transapical, percutaneous approach.
02RG38Z	Replacement of mitral valve with zooplastic tissue, percutaneous approach.
02RG3JH	Replacement of mitral valve with synthetic substitute, transapical, percutaneous approach.
02RG3JZ	Replacement of mitral valve with synthetic substitute, percutaneous approach.
02RG3KH	Replacement of mitral valve with nonautologous tissue substitute, transapical, percutaneous approach.
02RG3KZ	Replacement of mitral valve with nonautologous tissue substitute, percutaneous approach.
02RH37H	Replacement of pulmonary valve with autologous tissue substitute, transapical, percutaneous approach.
02RH37Z	Replacement of pulmonary valve with autologous tissue substitute, percutaneous approach.
02RH38H	Replacement of pulmonary valve with zooplastic tissue, transapical, percutaneous approach.
02RH38Z	Replacement of pulmonary valve with zooplastic tissue, percutaneous approach.
02RH3JH	Replacement of pulmonary valve with synthetic substitute, transapical, percutaneous approach.
02RH3JZ	Replacement of pulmonary valve with synthetic substitute, percutaneous approach.
02RH3KH	Replacement of pulmonary valve with nonautologous tissue substitute, transapical, percutaneous approach.
02RH3KZ	Replacement of pulmonary valve with nonautologous tissue substitute, percutaneous approach.
02RJ37H	Replacement of tricuspid valve with autologous tissue substitute, transapical, percutaneous approach.
02RJ37Z	Replacement of tricuspid valve with autologous tissue substitute, percutaneous approach.
02RJ38H	Replacement of tricuspid valve with zooplastic tissue, transapical, percutaneous approach.
02RJ38Z	Replacement of tricuspid valve with zooplastic tissue, percutaneous approach.
02RJ3JH	Replacement of tricuspid valve with synthetic substitute, transapical, percutaneous approach.
02RJ3JZ	Replacement of tricuspid valve with synthetic substitute, percutaneous approach.
02RJ3KH	Replacement of tricuspid valve with nonautologous tissue substitute, transapical, percutaneous approach.
02RJ3KZ	Replacement of tricuspid valve with nonautologous tissue substitute, percutaneous approach.
X2RF332	Replacement of aortic valve using zooplastic tissue, rapid deployment technique, percutaneous approach, new technology group 2.

The requestor performed its own analyses, first comparing TMVR procedures (ICD–10–PCS procedure code 02UG3JZ) to other procedures currently assigned to MS–DRGs 228 and 229, as well as to the transcatheter cardiac valve replacement procedures in MS–DRGs 266 and 267. We refer the reader to the ICD–10 MS–DRG Version 36 Definitions Manual for complete documentation of the logic for case assignment to MS–DRGs 228 and 229 (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html*). According to the requestor, its findings indicate that TMVR is more closely aligned with MS–DRGs 266 and 267 than MS–DRGs 228 and 229 with regard to average length of stay and average [standardized] costs. The requestor also examined the impact of removing cases reporting a TMVR procedure (ICD–10–PCS procedure code 02UG3JZ) from MS–DRGs 228 and 229 and adding those cases to MS–DRGs 266 and 267. The requestor noted this movement would have minimal impact to MS–DRGs 266 and 267 based on its analysis. In addition, the requestor stated that its request is in alignment with CMS' policy goal of creating and maintaining clinically coherent MS–DRGs.

The requestor acknowledged that CMS has indicated in prior rulemaking that TMVR procedures are not clinically similar to endovascular cardiac valve replacement procedures, and the requestor agreed that they are distinct procedures. However, the requestor also believed that TMVR is more similar to the replacement procedures in MS–DRGs 266 and 267 compared to the other procedures currently assigned to MS–DRGs 228 and 229. The requestor provided the following table of procedures in volume order (highest to lowest) to illustrate the clinical differences between TMVR procedures and other procedures currently assigned to MS–DRGs 228 and 229.

Procedure	Approach	Anatomy treated	ICD–10–PCS root operation	Implanted device
TMVR	Percutaneous	Valves	Supplement	Substitute.
Destruction	Open	Atria	Destruction	None.

Procedure	Approach	Anatomy treated	ICD–10–PCS root operation	Implanted device
Coronary Atherectomy	Open	Coronary Artery	Extirpation	None.
Insertion	Percutaneous	Atria or Ventricles	Insertion	Pacemaker or Intraluminal Device.
Destruction	Percutaneous	Atria	Destructions	None.
Structural Heart Repair	Open	Septum, Heart, Chordae Tendinae, or Papillary Muscle.	Repair	None.
Structural Heart Excision	Open	Septum, Atria, Ventricles, Chordae Tendinae, or Papillary Muscle.	Excision	None.

The requestor noted that, among the procedures listed in the table, TMVR is the only procedure that involves treatment of a cardiac valve and is the only procedure that involves implanting a synthetic substitute.

To illustrate the similarities between TMVR procedures and endovascular cardiac valve replacements in MS–DRGs 266 and 267, the requestor provided the following table.

Procedure	Approach	Anatomy treated	ICD–10–PCS root operation	Implanted device
TMVR	Percutaneous	Valves	Supplement	Substitute.
Endovascular Cardiac Valve Replacement.	Percutaneous	Valves	Replacement	Substitute.

The requestor noted that both TMVR procedures and endovascular cardiac valve replacements use a percutaneous approach, treat cardiac valves, and use an implanted device for purposes of improving the function of the specified valve. The requestor believed that the analyses support the request to group TMVR procedures with endovascular cardiac valve replacements from a resource perspective and an improvement to clinical coherence could be achieved because TMVR procedures are more similar to the endovascular cardiac valve replacements compared to the other procedures in MS–DRGs 228 and 229, where TMVR is currently assigned.

As noted earlier in this section, the request also included the suggestion that CMS give consideration to reclassifying other endovascular cardiac valve repair with implant procedures to MS–DRGs 266 and 267; specifically, endovascular cardiac valve repair with implant procedures involving the aortic, pulmonary, tricuspid and other non-TMVR mitral valve procedures that currently group to MS–DRGs 273 and 274 or MS–DRGs 216, 217, 218, 219, 220 and 221. The requestor acknowledged that endovascular cardiac valve repair with implant procedures involving these other cardiac valves have lower volumes in comparison to the TMVR procedure (ICD–10–PCS procedure code 02UG3JZ), which makes analysis of these procedures a little more difficult. However, the requestor suggested that movement of these procedures to MS–DRGs 266 and 267 would enable the ability to maintain clinical coherence for all endovascular cardiac valve interventions. The requestor also stated that there is an anticipated increase in the volume of not only the TMVR procedure described by ICD–10–PCS procedure code 02UG3JZ (which has grown annually since the MitraClip® was approved for new technology add-on payment in FY 2015), but also for the other endovascular cardiac valve repair with implant procedures, such as those involving the tricuspid valve, which are currently under study in the United States and Europe. Based on this anticipated increase in volume for endovascular cardiac valve repair with implant procedures, the requestor believed that it would be advantageous to take this opportunity to restructure the MS–DRGs by moving all the endovascular cardiac valve repair with implant procedures to MS–DRGs 266 and 267 with revised titles as noted previously, to improve clinical consistency beginning in FY 2020. The requestor further noted that while the requestor believes its request reflects the best approach for appropriate MS–DRG assignment for TMVR and other endovascular cardiac valve repair with implant procedures, the requestor understands that CMS may consider other alternatives.

We analyzed claims data from the September 2018 update of the FY 2018 MedPAR file for cases reporting ICD–10–PCS procedure code 02UG3JZ in MS–DRGs 228 and 229 as well as cases reporting one of the procedure codes listed above describing a transcatheter cardiac valve repair with implant procedure in MS–DRGs 216, 217, 218, 219, 220, 221, 273, and 274. Our findings are shown in the tables below.

MS–DRGs FOR TRANSCATHETER CARDIAC VALVE REPAIR WITH IMPLANT PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 216—All cases	5,909	16	$70,435
MS–DRG 216—Cases with procedure codes for transcatheter cardiac valve repair	48	12.6	72,556
MS–DRG 217—All cases	2,166	9.4	47,299
MS–DRG 217—Cases with procedure codes for transcatheter cardiac valve repair	25	3.4	40,707
MS–DRG 218—All cases	268	6.8	39,501
MS–DRG 218—Cases with procedure codes for transcatheter cardiac valve repair	4	1.3	45,903
MS–DRG 219—All cases	15,105	10.9	55,423
MS–DRG 219—Cases with procedure codes for transcatheter cardiac valve repair	55	7.1	65,880

MS–DRGs FOR TRANSCATHETER CARDIAC VALVE REPAIR WITH IMPLANT PROCEDURES—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 220—All cases	15,889	6.6	38,313
MS–DRG 220—Cases with procedure codes for transcatheter cardiac valve repair	40	3	38,906
MS–DRG 221—All cases	2,652	4.7	33,577
MS–DRG 221—Cases with procedure codes for transcatheter cardiac valve repair	13	2.2	29,646
MS–DRG 228—All cases	5,583	9.2	46,613
MS–DRG 228—Cases with procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach)	1,688	5.6	49,569
MS–DRG 229—All cases	6,593	4.3	32,322
MS–DRG 229—Cases with procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach)	2,018	1.7	38,321
MS–DRG 273—All cases	7,785	6.9	27,200
MS–DRG 273—Cases with procedure codes for transcatheter cardiac valve repair	6	7.5	52,370
MS–DRG 274—All cases	20,434	2.3	22,771
MS–DRG 274—Cases with procedure codes for transcatheter cardiac valve repair	7	1.4	28,152

As shown in the table, we found a total of 5,909 cases for MS–DRG 216 with an average length of stay of 16 days and average costs of $70,435. Of those 5,909 cases, there were 48 cases reporting a procedure code for a transcatheter cardiac valve repair with an average length of stay of 12.6 days and average costs of $72,556. We found a total of 2,166 cases for MS–DRG 217 with an average length of stay of 9.4 days and average costs of $47,299. Of those 2,166 cases, there was a total of 25 cases reporting a procedure for a transcatheter cardiac valve repair with an average length of stay of 3.4 days and average costs of $40,707. We found a total of 268 cases for MS–DRG 218 with an average length of stay of 6.8 days and average costs of $39,501. Of those 268 cases, there were 4 cases reporting a procedure code for a transcatheter cardiac valve repair with an average length of stay of 1.3 days and average costs of $45,903. We found a total of 15,105 cases for MS–DRG 219 with an average length of stay of 10.9 days and average costs of $55,423. Of those 15,105 cases, there were 55 cases reporting a procedure code for a transcatheter cardiac valve repair with an average length of stay of 7.1 days and average costs of $65,880. We found a total of 15,889 cases for MS–DRG 220 with an average length of stay of 6.6 days and average costs of $38,313. Of those 15,889 cases, there were 40 cases reporting a procedure code for a transcatheter cardiac valve repair with an average length of stay of 3 days and average costs of $38,906. We found a total of 2,652 cases for MS–DRG 221 with an average length of stay of 4.7 days and average costs of $33,577. Of those 2,652 cases, there were 13 cases reporting a procedure code for a transcatheter cardiac valve repair with an average length of stay of 2.2 days and average costs of $29,646.

For MS–DRG 228, we found a total of 5,583 cases with an average length of stay of 9.2 days and average costs of $46,613. Of those 5,583 cases, there were 1,688 cases reporting ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) with an average length of stay of 5.6 days and average costs of $49,569. As noted previously, ICD–10–PCS procedure code 02UG3JZ is the only endovascular cardiac valve repair with implant procedure assigned to MS–DRGs 228 and 229. We found a total of 6,593 cases for MS–DRG 229 with an average length of stay of 4.3 days and average costs of $32,322. Of those 6,593 cases, there were 2,018 cases reporting ICD–10–PCS procedure code 02UG3JZ with an average length of stay of 1.7 days and average costs of $38,321.

For MS–DRG 273, we found a total of 7,785 cases with an average length of stay of 6.9 days and average costs of $27,200. Of those 7,785 cases, there were 6 cases reporting a procedure code for a transcatheter cardiac valve repair with an average length of stay of 7.5 days and average costs of $52,370. We found a total of 20,434 cases in MS–DRG 274 with an average length of stay of 2.3 days and average costs of $22,771. Of those 20,434 cases, there were 7 cases reporting a procedure code for a transcatheter cardiac valve repair with an average length of stay of 1.4 days and average costs of $28,152.

We also analyzed cases reporting any one of the procedure codes listed above describing a transcatheter cardiac valve replacement procedure in MS–DRGs 266 and 267. Our findings are shown in the table below.

MS–DRGs FOR TRANSCATHETER CARDIAC VALVE REPLACEMENT PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 266—All cases	15,079	5.6	$51,402
MS–DRG 267—All cases	20,845	2.4	41,891

As shown in the table, there was a total of 15,079 cases with an average length of stay of 5.6 days and average costs of $51,402 in MS–DRG 266. For MS–DRG 267, there was a total of 20,845 cases with an average length of stay of 2.4 days and average costs of $41,891.

As stated previously, the requestor noted that ICD–10–PCS procedure code 02UG3JZ describing a transcatheter mitral valve repair with implant procedure is the only endovascular cardiac valve intervention with implant procedure assigned to MS–DRGs 228 and 229. The data analysis shows that for the cases reporting procedure code 02UG3JZ in MS–DRGs 228 and 229, the average length of stay and average costs are aligned with the average length of stay and average costs of cases in MS–DRGs 266 and 267, respectively.

The data also show that, for MS–DRGs 216, 217, 218, 219, 220, and 221 and for

MS–DRG 274, the average length of stay for cases reporting a transcatheter cardiac valve with implant procedure is shorter than the average length of stay for all the cases in their assigned MS–DRG. For MS–DRG 273, the average length of stay for cases reporting a transcatheter cardiac valve with implant procedure is slightly longer (7.5 days versus 6.9 days). In addition, the average costs for the cases reporting a transcatheter cardiac valve with implant procedure are higher when compared to all the cases in their assigned MS–DRG with the exception of MS–DRG 217 ($40,707 versus $47,299) and MS–DRG 221 ($29,646 versus $33,577).

Our clinical advisors continue to believe that transcatheter cardiac valve repair procedures are not the same as a transcatheter (endovascular) cardiac valve replacement. However, they agree with the requestor and, based on our data analysis, that these procedures are more clinically coherent in that they also describe endovascular cardiac valve interventions with implants and are similar in terms of average length of stay and average costs to cases in MS–DRGs 266 and 267 when compared to other procedures in their current MS–DRG assignment. For these reasons, our clinical advisors agree that we should propose to reassign the endovascular cardiac valve repair procedures (supplement procedures) listed previously to the endovascular cardiac valve replacement MS–DRGs.

We analyzed the impact of grouping the endovascular cardiac valve repair with implant (supplement) procedures with the endovascular cardiac valve replacement procedures. The following table reflects our findings for the proposed revised endovascular cardiac valve (supplement) procedures with the endovascular cardiac valve replacement MS–DRGs with a 2-way severity level split.

PROPOSED REVISED MS–DRGS FOR ENDOVASCULAR CARDIAC VALVE REPLACEMENT AND SUPPLEMENT PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 266 (Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC)	16,922	5.7	$51,564
MS–DRG 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC)	22,958	2.4	41,563.

As shown in the table, there was a total of 16,922 cases for the endovascular cardiac valve replacement and supplement procedures with MCC group, with an average length of stay of 5.7 days and average costs of $51,564. There was a total of 22,958 cases for the endovascular cardiac valve replacement and supplement procedures without MCC group, with an average length of stay of 2.4 days and average costs of $41,563. We applied the criteria to create subgroups for the two-way severity level split for the proposed revised MS–DRGs and found that all five criteria were met. For the proposed revised MS–DRGs, there is at least (1) 500 or more cases in the MCC group or in the without MCC subgroup; (2) 5 percent or more of the cases in the MCC group or in the without MCC subgroup; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

During our review of the transcatheter cardiac valve repair (supplement) procedures in MS–DRGs 216, 217, 218, 219, 220, and 221, MS–DRGs 228 and 229, and MS–DRGs 273 and 274, our clinical advisors recommended that we also analyze the claims data to identify other (non-supplement) transcatheter (endovascular) procedures that involve the cardiac valves and are assigned to those same MS–DRGs to determine if additional modifications may be warranted, consistent with our ongoing efforts to refine the ICD–10 MS–DRGs.

We analyzed the following ICD–10–PCS procedure codes that are currently assigned to MS–DRGs 216, 217, 218, 219, 220, and 221.

ICD–10–PCS code	Description
02QF3ZJ	Repair aortic valve created from truncal valve, percutaneous approach.
02QF3ZZ	Repair aortic valve, percutaneous approach.
02QG3ZE	Repair mitral valve created from left atrioventricular valve, percutaneous approach.
02QG3ZZ	Repair mitral valve, percutaneous approach.
02QH3ZZ	Repair pulmonary valve, percutaneous approach.
02QJ3ZG	Repair tricuspid valve created from right atrioventricular valve, percutaneous approach.
02QJ3ZZ	Repair tricuspid valve, percutaneous approach.
02TH3ZZ	Resection of pulmonary valve, percutaneous approach.
02VG3ZZ	Restriction of mitral valve, percutaneous approach.
02WF38Z	Revision of zooplastic tissue in aortic valve, percutaneous approach.
02WF3JZ	Revision of synthetic substitute in aortic valve, percutaneous approach.
02WF3KZ	Revision of nonautologous tissue substitute in aortic valve, percutaneous approach.
02WG37Z	Revision of autologous tissue substitute in mitral valve, percutaneous approach.
02WG38Z	Revision of zooplastic tissue in mitral valve, percutaneous approach.
02WG3JZ	Revision of synthetic substitute in mitral valve, percutaneous approach.
02WG3KZ	Revision of nonautologous tissue substitute in mitral valve, percutaneous approach.
02WH37Z	Revision of autologous tissue substitute in pulmonary valve, percutaneous approach.
02WH38Z	Revision of zooplastic tissue in pulmonary valve, percutaneous approach.
02WH3JZ	Revision of synthetic substitute in pulmonary valve, percutaneous approach.
02WH3KZ	Revision of nonautologous tissue substitute in pulmonary valve, percutaneous approach.
02WJ37Z	Revision of autologous tissue substitute in tricuspid valve, percutaneous approach.

ICD–10–PCS code	Description
02WJ38Z	Revision of zooplastic tissue in tricuspid valve, percutaneous approach.
02WJ3JZ	Revision of synthetic substitute in tricuspid valve, percutaneous approach.
02WJ3KZ	Revision of nonautologous tissue substitute in tricuspid valve, percutaneous approach.

We also analyzed ICD–10–PCS procedure code 02TH3ZZ (Resection of pulmonary valve, percutaneous approach) that is currently assigned to MS–DRGs 228 and 229. Lastly, we analyzed the following ICD–10–PCS procedure codes that are currently assigned to MS–DRGs 273 and 274.

ICD–10–PCS code	Description
025F3ZZ	Destruction of aortic valve, percutaneous approach.
025G3ZZ	Destruction of mitral valve, percutaneous approach.
025H3ZZ	Destruction of pulmonary valve, percutaneous approach.
025J3ZZ	Destruction of tricuspid valve, percutaneous approach.
027F34Z	Dilation of aortic valve with drug-eluting intraluminal device, percutaneous approach.
027F3DZ	Dilation of aortic valve with intraluminal device, percutaneous approach.
027F3ZZ	Dilation of aortic valve, percutaneous approach.
027G34Z	Dilation of mitral valve with drug-eluting intraluminal device, percutaneous approach.
027G3DZ	Dilation of mitral valve with intraluminal device, percutaneous approach.
027G3ZZ	Dilation of mitral valve, percutaneous approach.
027H34Z	Dilation of pulmonary valve with drug-eluting intraluminal device, percutaneous approach.
027H3DZ	Dilation of pulmonary valve with intraluminal device, percutaneous approach.
027H3ZZ	Dilation of pulmonary valve, percutaneous approach.
027J34Z	Dilation of tricuspid valve with drug-eluting intraluminal device, percutaneous approach.
027J3DZ	Dilation of tricuspid valve with intraluminal device, percutaneous approach.
027J3ZZ	Dilation of tricuspid valve, percutaneous approach.
02BF3ZZ	Excision of aortic valve, percutaneous approach.
02BG3ZZ	Excision of mitral valve, percutaneous approach.
02BH3ZZ	Excision of pulmonary valve, percutaneous approach.
02BJ3ZZ	Excision of tricuspid valve, percutaneous approach.

We analyzed claims data from the September 2018 update of the FY 2018 MedPAR file for cases reporting any of the above listed procedure codes in MS–DRGs 216, 217, 218, 219, 220, and 221, MS–DRGs 228 and 229, and MS–DRGs 273 and 274. Our findings are shown in the following tables. We note that there were no cases found in MS–DRGs 228 and 229 reporting ICD–10–PCS procedure code 02TH3ZZ (Resection of pulmonary valve, percutaneous approach).

OTHER CARDIAC VALVE PROCEDURES IN MS–DRGS 216 THROUGH 221

ICD–10–PCS code	Description	Number of times reported	Average length of stay	Average costs
02QF3ZZ	Repair aortic valve, percutaneous approach	58	9.7	$33,588
02QG3ZE	Repair mitral valve created from left atrioventricular valve, percutaneous approach.	4	1.3	38,680
02QG3ZZ	Repair mitral valve, percutaneous approach	40	3.4	30,160
02QH3ZZ	Repair pulmonary valve, percutaneous approach	1	1	33,014
02QJ3ZG	Repair tricuspid valve created from right atrioventricular valve, percutaneous approach.	1	9	51,294
02QJ3ZZ	Repair tricuspid valve, percutaneous approach	15	5	25,208
02VG3ZZ	Restriction of mitral valve, percutaneous approach	11	8.1	53,798
02WF38Z	Revision of zooplastic tissue in aortic valve, percutaneous approach	26	8.9	61,124
02WF3JZ	Revision of synthetic substitute in aortic valve, percutaneous approach	37	7.1	26,605
02WF3KZ	Revision of nonautologous tissue substitute in aortic valve, percutaneous approach.	2	1	69,030
02WG38Z	Revision of zooplastic tissue in mitral valve, percutaneous approach	2	7.5	16,982
02WG3JZ	Revision of synthetic substitute in mitral valve, percutaneous approach	31	7.3	28,682
02WH3JZ	Revision of synthetic substitute in pulmonary valve, percutaneous approach.	1	6	30,340
02WJ3JZ	Revision of synthetic substitute in tricuspid valve, percutaneous approach	1	3	14,145
Total		230	7.1	34,968

OTHER CARDIAC VALVE PROCEDURES IN MS–DRGS 273 AND 274

ICD–10–PCS code	Description	Number of times reported	Average length of stay	Average costs
025F3ZZ	Destruction of aortic valve, percutaneous approach	6	4.7	$11,130

OTHER CARDIAC VALVE PROCEDURES IN MS–DRGS 273 AND 274—Continued

ICD–10–PCS code	Description	Number of times reported	Average length of stay	Average costs
025J3ZZ	Destruction of tricuspid valve, percutaneous approach	21	3.9	18,320
027F34Z	Dilation of aortic valve with drug-eluting intraluminal device, percutaneous approach.	1	16	53,786
027F3DZ	Dilation of aortic valve with intraluminal device, percutaneous approach	5	8.4	20,951
027F3ZZ	Dilation of aortic valve, percutaneous approach	1,720	8.6	25,265
027G3ZZ	Dilation of mitral valve, percutaneous approach	86	6.4	19,791
027H3ZZ	Dilation of pulmonary valve, percutaneous approach	5	3.8	10,506
02BJ3ZZ	Excision of tricuspid valve, percutaneous approach	1	4	30,843
Total		1,845	8.4	24,851

We found that the overall frequency with which cases reporting at least one of the above ICD–10–PCS procedure codes were reflected in the claims data was 2,075 times with an average length of stay of 8.5 days and average costs of $27,838. ICD–10–PCS procedure code 027F3ZZ (Dilation of aortic valve, percutaneous approach) had the highest frequency of 1,720 times with an average length of stay of 8.6 days and average costs of $25,265. We also found that cases reporting ICD–10–PCS procedure code 02WF3KZ (Revision of nonautologous tissue substitute in aortic valve, percutaneous approach) had the highest average costs of $69,030 with an average length of stay of 1 day. While not displayed above, we also note that, of the 7,785 cases found in MS–DRG 273, from the remaining procedure codes describing procedures other than those performed on a cardiac valve, there were 4,920 cases reporting ICD–10–PCS procedure code 02583ZZ (Destruction of conduction mechanism, percutaneous approach) with an average length of stay of 6.6 days and average costs of $26,800, representing approximately 63 percent of all the cases in that MS–DRG. In addition, of the 20,434 cases in MS–DRG 274, from the remaining procedure codes describing procedures other than those performed on a cardiac valve, there were 9,268 cases reporting ICD–10–PCS procedure code 02583ZZ (Destruction of conduction mechanism, percutaneous approach) with an average length of stay of 3.2 days and average costs of $21,689, and 8,775 cases reporting ICD–10–PCS procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) with an average length of stay of 1.2 days and average costs of $25,476, representing approximately 88 percent of all the cases in that MS–DRG.

After analyzing the claims data to identify the overall frequency with which the other (non-supplement) ICD–10–PCS procedure codes describing a transcatheter (endovascular) cardiac valve procedure were reported and assigned to MS–DRGs 216, 217, 218, 219, 220, and 221, MS–DRGs 228 and 229, and MS–DRGs 273 and 274, our clinical advisors suggested that these other cardiac valve procedures should be grouped together because the procedure codes are describing procedures performed on a cardiac valve with a percutaneous (transcatheter/endovascular) approach, they can be performed in a cardiac catheterization laboratory, they require that the interventional cardiologist have special additional training and skills, and often require additional ancillary procedures and equipment, such as trans-esophageal echocardiography, be available at the time of the procedure. Our clinical advisors noted that these procedures are generally considered more complicated and resource-intensive, and form a clinically coherent group. They also noted that the majority of procedures currently being reported in MS–DRGs 273 and 274 are procedures other than those involving a cardiac valve and, therefore, believed that reassignment of the other (non-supplement) ICD–10–PCS procedure codes describing a transcatheter (endovascular) cardiac valve procedure would have minimal impact to those MS–DRGs.

We then analyzed the impact of grouping the other transcatheter cardiac valve procedures. The following table reflects our findings for the suggested other endovascular cardiac valve procedures MS–DRGs with a 2-way severity level split.

SUGGESTED MS–DRGS FOR OTHER ENDOVASCULAR CARDIAC VALVE PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG XXX (Other Endovascular Cardiac Valve Procedures with MCC)	1,527	9.7	$27,801
MS–DRG XXX (Other Endovascular Cardiac Valve Procedures without MCC)	560	3.9	17,027

As shown in the table, there were 1,527 cases for the other endovascular cardiac valve procedures with MCC group, with an average length of stay of 9.7 days and average costs of $27,801. There was a total of 560 cases for the other endovascular cardiac valve procedures without MCC group, with an average length of stay of 3.9 days and average costs of $17,027. We applied the criteria to create subgroups for the two-way severity level split for the suggested MS–DRGs and found that all five criteria were met. For the suggested MS–DRGs, there is at least (1) 500 or more cases in the MCC group or in the without MCC subgroup; (2) 5 percent or more of the cases in the MCC group or in the without MCC subgroup; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) at least a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

For FY 2020, we are proposing to modify the structure of MS–DRGs 266 and 267 by reassigning the procedure codes describing a transcatheter cardiac valve repair (supplement) procedure from the list above and to revise the title of these MS–DRGs. We are proposing to revise the title of MS–DRGs 266 from ''Endovascular Cardiac Valve Replacement with MCC'' to ''Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC'' and the title of MS–DRG 267 from ''Endovascular Cardiac Valve Replacement without MCC'' to ''Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC'', to reflect the proposed restructuring. We also are proposing to create two new MS–DRGs with a two-way severity level split for the remaining (non-supplement) transcatheter cardiac valve procedures listed above. These proposed new MS–DRGs are proposed new MS–DRG 319 (Other Endovascular Cardiac Valve Procedures with MCC) and proposed new MS–DRG 320 (Other Endovascular Cardiac Valve Procedures without MCC), which would also conform with the severity level split of MS–DRGs 266 and 267. We are proposing to reassign the procedure codes from their current MS–DRGs to the proposed new MS–DRGs.

b. Revision of Pacemaker Lead

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41189 through 41190), we finalized our proposal to maintain the Version 35 ICD–10 MS–DRG GROUPER logic for the Version 36 ICD–10 MS–DRG GROUPER logic within MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC and without CC/MCC, respectively) so that cases reporting any of the ICD–10–PCS procedure codes describing procedures involving pacemakers and related procedures and associated devices would continue to be assigned to those MS–DRGs under MDC 5 because they are reported when a pacemaker device requires revision and they have a corresponding circulatory system diagnosis. We also discussed and finalized the addition of ICD–10–PCS procedure codes 02H63MZ (Insertion of cardiac lead into right atrium, percutaneous approach) and 02H73MZ (Insertion of cardiac lead into left atrium, percutaneous approach) to the GROUPER logic as non-O.R. procedures that impact the MS–DRG assignment when reported as stand-alone codes for the insertion of a pacemaker lead within MS–DRGs 260, 261, and 262 in response to a commenter's suggestion.

After publication of the FY 2019 IPPS/LTCH PPS final rule, it was brought to our attention that ICD–10–PCS procedure code 02H60JZ (Insertion of pacemaker lead into right atrium, open approach) was inadvertently omitted from the GROUPER logic for MS–DRGs 260, 261, and 262. This procedure code is designated as a non-O.R. procedure. However, we note that, within MDC 5, in MS–DRGs 242, 243, and 244, this procedure code is part of a code pair that requires another procedure code (cluster). We are proposing to add procedure code 02H60JZ to the list of non-O.R. procedures that would impact MS–DRGs 260, 261, and 262 when reported as a stand-alone procedure code, consistent with ICD–10–PCS procedure codes 02H63JZ (Insertion of pacemaker lead into right atrium, percutaneous approach) and 02H64JZ (Insertion of pacemaker lead into right atrium, percutaneous endoscopic approach), which also describe the insertion of a pacemaker lead into the right atrium. If the proposal is finalized, we would make conforming changes to the ICD–10 MS–DRG Definitions Manual Version 37.

6. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Knee Procedures With Principal Diagnosis of Infection

We received a request to add ICD–10–CM diagnosis codes M00.9 (Pyogenic arthritis, unspecified) and A54.42 (Gonococcal arthritis) to the list of principal diagnoses for MS–DRGs 485, 486, and 487 (Knee Procedure with Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively) in MDC 8. The requestor believed that adding diagnosis code M00.9 is necessary to accurately recognize knee procedures that are performed with a principal diagnosis of infectious arthritis, including those procedures performed when the specific infectious agent is unknown. The requestor stated that, currently, only diagnosis codes describing infections caused by a specific bacterium are included in MS–DRGs 485, 486, and 487. The requestor stated that additional diagnosis codes such as M00.9 are indicated for knee procedures performed as a result of infection because pyogenic arthritis can reasonably be diagnosed based on the patient's history and clinical symptoms, even if a bacterial infection is not confirmed by culture. For example, the requestor noted that a culture may present negative for infection if a patient has been treated with antibiotics prior to knee surgery, but other clinical signs may indicate a principal diagnosis of joint infection. In the absence of a culture identifying an infection by a specific bacterium, the requestor stated that ICD–10–CM diagnosis code M00.09 should also be included as a principal diagnosis in MS–DRGs 485, 486, and 487.

The requestor also asserted that ICD–10–CM diagnosis code A54.42 should be added to the list of principal diagnoses for MS–DRGs 485, 486, and 487 because gonococcal arthritis is also an infectious type of arthritis that can be an indication for a knee procedure.

Currently, cases reporting ICD–10–CM diagnosis codes M00.9 or A54.42 as a principal diagnosis group to MS–DRGs 488 and 489 (Knee Procedures without Principal Diagnosis of Infection with and without CC/MCC, respectively) when a knee procedure is also reported on the claim.

We analyzed claims data from the September 2018 update of the FY 2018 MedPAR file for ICD–10–CM diagnosis codes M00.9 and A54.42, which are currently assigned to medical MS–DRGs 548, 549, and 550 (Septic Arthritis with MCC, with CC, and without CC/MCC, respectively) in the absence of a surgical procedure. Our findings are shown in the following table.

MS–DRGs FOR SEPTIC ARTHRITIS WITH PYOGENIC ARTHRITIS OR GONOCOCCAL ARTHRITIS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 548—All cases	601	8.1	$13,974
MS–DRG 548—Cases with pyogenic arthritis as principal diagnosis	312	7.6	13,177
MS–DRG 549—All cases	1,169	5.0	8,547
MS–DRG 549—Cases with pyogenic arthritis as principal diagnosis	686	4.7	7,976
MS–DRG 549—Cases with gonococcal arthritis as principal diagnosis	2	8.0	7,070
MS–DRG 550—All cases	402	3.5	6,317

MS–DRGs FOR SEPTIC ARTHRITIS WITH PYOGENIC ARTHRITIS OR GONOCOCCAL ARTHRITIS—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 550—Cases with pyogenic arthritis as principal diagnosis	260	3.2	6,209
MS–DRG 550—Cases with gonococcal arthritis as principal diagnosis	3	2.3	3,929

As shown in the table, we found a total of 2,172 cases in MS–DRGs 548, 549, and 550. A total of 601 cases were reported in MS–DRG 548, with an average length of stay of 8.1 days and average costs of $13,974. Cases in MS–DRG 548 with a principal diagnosis of pyogenic arthritis (ICD–10–CM diagnosis code M00.9) accounted for 312 of these 601 cases, and reported an average length of stay of 7.6 days and average costs of $13,177. None of the cases in MS–DRG 548 had a principal diagnosis of gonococcal arthritis (ICD–10–CM diagnosis code A54.42).

The total number of cases reported in MS–DRG 549 was 1,169, with an average length of stay of 5 days and average costs of $8,547. Within this MS–DRG, 686 cases had a principal diagnosis described by ICD–10–CM diagnosis code M00.9, with an average length of stay of 4.7 days and average costs of $7,976. Two of the cases reported in MS–DRG 549 had a principal diagnosis described by ICD–10–CM diagnosis code A54.42. These 2 cases had an average length of stay of 8 days and average costs of $7,070.

The total number of cases reported in MS–DRG 550 was 402, with an average length of stay of 3.5 days and average costs of $6,317. Within this MS–DRG, 260 cases had a principal diagnosis described by ICD–10–CM diagnosis code M00.9 with an average length of stay of 3.2 days and average costs of $6,209. Three of the cases reported in MS–DRG 550 had a principal diagnosis described by ICD–10–CM diagnosis code A54.42. These 3 cases had an average length of stay of 2.3 days and average costs of $3,929.

In summary, for MS–DRGs 548, 549, and 550, there were 1,258 cases that reported ICD–10–CM diagnosis code M00.9 as the principal diagnosis and 5 cases that reported ICD–10–CM diagnosis code A54.42 as the principal diagnosis. We note that, overall, our data analysis suggests that the MS–DRG assignment for cases reporting ICD–10–CM diagnosis codes M00.9 and A54.42 is appropriate based on the average costs and average length of stay. However, it is unclear how many of these cases involved infected knee joints because neither ICD–10–CM diagnosis code M00.9 nor A54.42 is specific to the knee. We then analyzed claims data for MS–DRGs 485, 486, and 487 (Knee Procedures with Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively) and for MS–DRGs 488 and 489 (Knee Procedures without Principal Diagnosis of Infection with and without CC/MCC, respectively). For MS–DRGs 488 and 489, we also analyzed claims data for cases reporting a knee procedure with ICD–10–CM diagnosis code M00.9 or A54.42 as a principal diagnosis, as these are the MS–DRGs to which such cases would currently group. Our findings are shown in the following table.

MS–DRGs FOR KNEE PROCEDURES WITH AND WITHOUT INFECTION

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 485—All cases	1,021	9.7	$23,980
MS–DRG 486—All cases	2,260	6	16,060
MS–DRG 487—All cases	614	4.2	12,396
MS–DRG 488—All cases	2,857	4.8	14,197
MS–DRG 488—Cases with pyogenic arthritis as principal diagnosis	524	7.1	16,894
MS–DRG 489—All cases	2,416	2.4	9,217
MS–DRG 489—Cases with pyogenic arthritis as principal diagnosis	195	4.1	9,526
MS–DRG 489—Cases with gonococcal arthritis as principal diagnosis	1	8	10,810

As shown in the table, we found a total of 1,021 cases reported in MS–DRG 485, with an average length of stay of 9.7 days and average costs of $23,980. We found a total of 2,260 cases reported in MS–DRG 486, with an average length of stay of 6.0 days and average costs of $16,060. The total number of cases reported in MS–DRG 487 was 614, with an average length of stay of 4.2 days and average costs of $12,396. For MS–DRG 488, we found a total of 2,857 cases with an average length of stay of 4.8 days and average costs of $14,197. Of these 2,857 cases, we found 524 cases that reported a principal diagnosis of pyogenic arthritis (ICD–10–CM diagnosis code M00.9), with an average length of stay of 7.1 days and average costs of $16,894. There were no cases found that reported a principal diagnosis of gonococcal arthritis (ICD–10–CM diagnosis code A54.42). For MS–DRG 489, we found a total of 2,416 cases with an average length of stay of 2.4 days and average costs of $9,217. Of these 2,416 cases, we found 195 cases that reported a principal diagnosis of pyogenic arthritis (ICD–10–CM diagnosis code M00.9), with an average length of stay of 4.1 days and average costs of $9,526. We found 1 case that reported a principal diagnosis of gonococcal arthritis (ICD–10–CM diagnosis code A54.42) in MS–DRG 489, with an average length of stay of 8 days and average costs of $10,810.

Upon review of the data, we noted that the average costs and average length of stay for cases reporting a principal diagnosis of pyogenic arthritis (ICD–10–CM diagnosis code M00.9) in MS–DRG 488 are higher than the average costs and average length of stay for all cases in MS–DRG 488. We found similar results for MS–DRG 489 for the cases reporting diagnosis code M00.9 or A54.42 as the principal diagnosis.

As stated earlier, the requestor recommended that ICD–10–CM diagnosis codes M00.9 and A54.42 be added to the list of principal diagnoses in MS–DRGs 485, 486, and 487 to recognize knee procedures that are performed with a principal diagnosis of an infectious type of arthritis. Because these diagnosis codes are not specific to the knee in the code description, we

examined the ICD–10–CM Alphabetic Index to review the entries that refer and correspond to these diagnosis codes. Specifically, we searched the Index for codes M00.9 and A54.42 and found the following entries.

Index entries referring to M00.9
Abscess (connective tissue) (embolic) (fistulous) (infective) (metastatic) (multiple) (pernicious) (pyogenic) (septic) > knee > joint
Arthritis, arthritic (acute) (chronic) (nonpyogenic) (subacute) > pyogenic or pyemic (any site except spine)
Disease, diseased > hip (joint) > suppurative
Infection, infected, infective (opportunistic) > acromioclavicular
Infection, infected, infective (opportunistic) > hip (joint) NEC Infection, infected, infective (opportunistic) > joint NEC
Infection, infected, infective (opportunistic) > knee (joint) NEC
Infection, infected, infective (opportunistic) > knee (joint) NEC > joint
Infection, infected, infective (opportunistic) > metatarsophalangeal
Infection, infected, infective (opportunistic) > shoulder (joint) NEC
Index entries referring to A54.42
Arthritis, arthritic (acute) (chronic) (nonpyogenic) (subacute) > blennorrhagic (gonococcal)
Arthritis, arthritic (acute) (chronic) (nonpyogenic) (subacute) > gonococcal
Gonococcus, gonococcal (disease) (infection) > joint
Gonococcus, gonococcal (disease) (infection) > musculoskeletal > arthritis
Hydrarthrosis > gonococcal
Periarthritis (joint) > gonococcal

Our clinical advisors agreed that the results of our ICD–10–CM Alphabetic Index review combined with the data analysis results support the addition of ICD–10–CM diagnosis code M00.9 to the list of principal diagnoses of infection for MS–DRGs 485, 486, and 487. The entries for diagnosis code M00.9 include infection of the knee, and as discussed above, in our data analysis, we found cases reporting ICD–10–CM diagnosis code M00.9 as a principal diagnosis in MS–DRGs 488 and 489, indicating that knee procedures are, in fact, being performed for an infectious arthritis of the knee. In addition, the average costs for cases reporting a principal diagnosis code of pyogenic arthritis (ICD–10–CM diagnosis code M00.9) in MS–DRG 488 are similar to the average costs of cases in MS–DRG 486 ($16,894 and $16,060, respectively). Because MS–DRG 488 includes cases with a CC or an MCC, we reviewed how many of the 524 cases reporting a principal diagnosis code of pyogenic arthritis (ICD–10–CM diagnosis code M00.9) were reported with a CC or an MCC. We found that there were 361 cases reporting a CC with an average length of stay of 6 days and average costs of $14,092 and 163 cases reporting an MCC with an average length of stay of 9.5 days and average costs of $23,100. Therefore, the cases in MS–DRG 488 reporting a principal diagnosis code of pyogenic arthritis (ICD–10–CM diagnosis code M00.9) with an MCC have average costs that are consistent with the average costs of cases in MS–DRG 485 ($23,100 and $23,980, respectively), and the cases with a CC have average costs that are consistent with the average costs of cases in MS–DRG 486 ($14,092 and $16,060, respectively), as noted above.

We also note that the average length of stay for cases reporting a principal diagnosis code of pyogenic arthritis (ICD–10–CM diagnosis code M00.9) with an MCC in MS–DRG 488 is similar to the average length of stay for cases in MS–DRG 485 (9.5 days and 9.7 days, respectively), and the cases with a CC have an average length of stay that is equivalent to the average length of stay for cases in MS–DRG 486 (6 days and 6 days, respectively). We further note that the average length of stay for cases reporting a principal diagnosis code of pyogenic arthritis (ICD–10–CM diagnosis code M00.9) in MS–DRG 489 is similar to the average length of stay for cases in MS DRG 487 (4.1 days and 4.2 days, respectively). Lastly, the average costs for cases reporting a principal diagnosis code of pyogenic arthritis (ICD–10–CM diagnosis code M00.9) in MS–DRG 489 are consistent with the average costs for cases in MS–DRG 487 ($9,526 and $12,396, respectively), with a difference of $2,870. For these reasons, we are proposing to add ICD–10–CM diagnosis code M00.9 to the list of principal diagnosis codes for MS–DRGs 485, 486, and 487.

Our clinical advisors did not support the addition of ICD–10–CM diagnosis code A54.42 to the list of principal diagnosis codes for MS–DRGs 485, 486, and 487 because ICD–10–CM diagnosis code A54.42 is not specifically indexed to include the knee or any infection in the knee. Therefore, we are not proposing to add ICD–10–CM diagnosis code A54.42 to the list of principal diagnosis codes for these MS–DRGs.

Upon review of the existing list of principal diagnosis codes for MS–DRGs 485, 486, and 487, our clinical advisors recommended that we review the following ICD–10–CM diagnosis codes currently included on the list of principal diagnosis codes because the codes are not specific to the knee.

ICD–10–CM code	Code description
M86.9	Osteomyelitis, unspecified.
T84.50XA	Infection and inflammatory reaction due to unspecified internal joint prosthesis, initial encounter.
T84.51XA	Infection and inflammatory reaction due to internal right hip prosthesis, initial encounter.
T84.52XA	Infection and inflammatory reaction due to internal left hip prosthesis, initial encounter.
T84.59XA	Infection and inflammatory reaction due to other internal joint prosthesis, initial encounter.
T84.60XA	Infection and inflammatory reaction due to internal fixation device of unspecified site, initial encounter.
T84.63XA	Infection and inflammatory reaction due to internal fixation device of spine, initial encounter.
T84.69XA	Infection and inflammatory reaction due to internal fixation device of other site, initial encounter.

These ICD–10–CM diagnosis codes are currently assigned to medical MS–DRGs 559, 560, and 561 (Aftercare, Musculoskeletal System and Connective Tissue with MCC, with CC, and without CC/MCC, respectively) within MDC 8 in the absence of a surgical procedure. Similar to the process described above, we examined the ICD–10–CM Alphabetic Index to review the entries that refer and correspond to the diagnosis codes shown in the table above. We found the following entries.

Index entries referring to M86.9: Osteomyelitis (general) (infective) (localized) (neonatal) (purulent) (septic) (staphylococcal) (streptococcal) (suppurative) (with periostitis).
Index entries referring to T84.50XA:Complication(s) (from) (of) > joint prosthesis, internal > infection or inflammation Infection, infected, infective (opportunistic) > joint NEC > due to internal joint prosthesis.
Index entries referring to T84.51XA: Infection, infected, infective (opportunistic) > hip (joint) NEC > due to internal joint prosthesis > right.
Index entries referring to T84.52XA: Infection, infected, infective (opportunistic) > hip (joint) NEC > due to internal joint prosthesis > left.
Index entries referring to T84.59XA: Complication(s) (from) (of) > joint prosthesis, internal > infection or inflammation > specified joint NEC Infection, infected, infective (opportunistic) > shoulder (joint) NEC > due to internal joint prosthesis.
Index entries referring to T84.60XA: Complication(s) (from) (of) > fixation device, internal (orthopedic) > infection and inflammation.
Index entries referring to T84.63XA: Complication(s) (from) (of) > fixation device, internal (orthopedic) > infection and inflammation > spine.
Index entries referring to T84.69XA: Complication(s) (from) (of) > fixation device, internal (orthopedic) > infection and inflammation > specified site NEC.

The Index entries for the ICD–10–CM diagnosis codes listed above reflect terms relating to an infection. However, none of the entries is specific to the knee. In addition, we note that there are other diagnosis codes in the subcategory T84.5– series (Infection and inflammatory reaction due to internal joint prosthesis) that are specific to the knee. For example, ICD–10–CM diagnosis code T84.53X– (Infection and inflammatory reaction due to internal right knee prosthesis) or ICD–10–CM diagnosis code T84.54X– (Infection and inflammatory reaction due to internal left knee prosthesis) with the appropriate 7th digit character to identify initial encounter, subsequent encounter or sequela, would be reported to identify a documented infection of the right or left knee due to an internal prosthesis. We further note that these ICD–10–CM diagnosis codes (T84.53X– and T84.54X–) with the 7th character ''A'' for initial encounter are currently already in the list of principal diagnosis codes for MS–DRGs 485, 486, and 487.

Our clinical advisors support the removal of the above ICD–10–CM diagnosis codes from the list of principal diagnosis codes for MS–DRGs 485, 486, and 487 because they are not specifically indexed to include an infection of the knee and there are other diagnosis codes in the subcategory T84.5– series that uniquely identify an infection and inflammatory reaction of the right or left knee due to an internal prosthesis as noted above.

We also analyzed claims data for MS–DRGs 485, 486 and 487 to identify cases reporting one of the above listed ICD–10–CM diagnosis codes not specific to the knee as a principal diagnosis. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 485—Cases reporting principal diagnosis code not specific to the knee	13	11.2	$30,765
MS–DRG 486—Cases reporting principal diagnosis code not specific to the knee	43	6.5	15,837
MS–DRG 487—Cases reporting principal diagnosis code not specific to the knee	7	2.6	11,362

For MS–DRG 485, we found 13 cases reporting one of the diagnosis codes not specific to the knee as a principal diagnosis with an average length of stay of 11.2 days and average costs of $30,765. For MS–DRG 486, we found 43 cases reporting one of the diagnosis codes not specific to the knee as a principal diagnosis with an average length of stay of 6.5 days and average costs of $15,837. For MS–DRG 487, we found 7 cases reporting one of the diagnosis codes not specific to the knee as a principal diagnosis with an average length of stay of 2.6 days and average costs of $11,362.

Overall, for MS–DRGs 485, 486, and 487, there were a total of 63 cases reporting one of the ICD–10–CM diagnosis codes not specific to the knee as a principal diagnosis with an average length of stay of 7 days and average costs of $18,421. Of those 63 cases, there were 32 cases reporting a principal diagnosis code from the ICD–10–CM subcategory T84.5-series (Infection and inflammatory reaction due to internal joint prosthesis); 23 cases reporting a principal diagnosis code from the ICD–10–CM subcategory T84.6-series (Infection and inflammatory reaction due to internal fixation device), with 22 of the 23 cases reporting ICD–10–CM diagnosis code T84.69XA (Infection and inflammatory reaction due to internal fixation device of other site, initial encounter) and 1 case reporting ICD–10–CM diagnosis code T84.63XA (Infection and inflammatory reaction due to internal fixation device of spine, initial encounter); and 8 cases reporting ICD–10–CM diagnosis code M86.9 (Osteomyelitis, unspecified) as a principal diagnosis.

Our clinical advisors believe that there may have been coding errors among the 63 cases reporting a principal diagnosis of infection not specific to the knee. For example, 32 cases reported a principal diagnosis code from the ICD–10–CM subcategory T84.5-series (Infection and inflammatory reaction due to internal joint prosthesis) that was not specific to the knee and, as stated previously, there are other codes in this subcategory that uniquely identify an infection and inflammatory reaction of the right or left knee due to an internal prosthesis.

Based on the results of our claims analysis and input from our clinical advisors, we are proposing to remove the following ICD–10–CM diagnosis codes that do not describe an infection of the knee from the list of principal diagnosis codes for MS–DRGs 485, 486, and 487: M86.9; T84.50XA; T84.51XA; T84.52XA; T84.59XA; T84.60XA; T84.63XA; and T84.69XA. We are not proposing to change the current assignment of these diagnosis codes in MS–DRGs 559, 560, and 561.

In addition, our clinical advisors recommended that we add the following ICD–10–CM diagnosis codes as principal diagnosis codes for MS–DRGs 485, 486, and 487 because they are specific to the knee and describe an infection.

ICD–10–CM code	Code description
A18.02	Tuberculous arthritis of other joints.
M01.X61	Direct infection of right knee in infectious and parasitic diseases classified elsewhere.
M01.X62	Direct infection of left knee in infectious and parasitic diseases classified elsewhere.
M01.X69	Direct infection of unspecified knee in infectious and parasitic diseases classified elsewhere.
M71.061	Abscess of bursa, right knee.
M71.062	Abscess of bursa, left knee.
M71.069	Abscess of bursa, unspecified knee.
M71.161	Other infective bursitis, right knee.
M71.162	Other infective bursitis, left knee.
M71.169	Other infective bursitis, unspecified knee.

ICD–10–CM diagnosis code A18.02 (Tuberculous arthritis of other joints) is currently assigned to medical MS–DRGs 548, 549, and 550 (Septic Arthritis with MCC, with CC, and without CC/MCC, respectively) within MDC 8 and MS–DRGs 974, 975, and 976 (HIV with Major Related Condition with MCC, with CC, and without CC/MCC, respectively) within MDC 25 (Human Immunodeficiency Virus Infections) in the absence of a surgical procedure. ICD–10–CM diagnosis codes M01.X61 (Direct infection of right knee in infectious and parasitic diseases classified elsewhere), M01.X62 (Direct infection of left knee in infectious and parasitic diseases classified elsewhere), and M01.X69 (Direct infection of unspecified knee in infectious and parasitic diseases classified elsewhere) are currently assigned to medical MS–DRGs 548, 549, and 550 (Septic Arthritis with MCC, with CC, and without CC/MCC, respectively) within MDC 8 in the absence of a surgical procedure. ICD–10–CM diagnosis codes M71.061 (Abscess of bursa, right knee), M71.062 (Abscess of bursa, left knee), M71.069 (Abscess of bursa, unspecified knee), M71.161 (Other infective bursitis, right knee), M71.162 (Other infective bursitis, left knee), and M71.169 (Other infective bursitis, unspecified knee) are currently assigned to medical MS–DRGs 557 and 558 (Tendonitis, Myositis and Bursitis with and without MCC, respectively) within MDC 8 in the absence of a surgical procedure.

Similar to the process described above, we examined the ICD–10–CM Alphabetic Index to review the entries that refer and correspond to the diagnosis codes shown in the table above. We found the following entries.

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Index entries referring to A18.02:
Arthritis, arthritic (acute) (chronic) (nonpyogenic) (subacute) > tuberculous

Caries > hip (tuberculous)

Caries > knee (tuberculous)

Chondritis > tuberculous NEC

Coxalgia, coxalgic (nontuberculous) > tuberculous

Cyst (colloid) (mucous) (simple) (retention) > Baker's > tuberculous

Disease, diseased > hip (joint) > tuberculous

Inflammation, inflamed, inflammatory (with exudation) > knee (joint) > tuberculous

Morbus > coxae senilis > tuberculous

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > abscess (respiratory) > bone > hip

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > abscess (respiratory) > bone > knee

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > abscess (respiratory) > hip

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > abscess (respiratory) > joint NEC

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > abscess (respiratory) > joint NEC > hip

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic

acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > abscess (respiratory) > joint NEC > knee

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > abscess (respiratory) > joint NEC > specified NEC

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > abscess (respiratory) > knee

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > ankle (joint) (bone)

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > arthritis (chronic) (synovial)

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > bone > hip

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > bone > knee

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > cartilage

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > coxae

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > coxalgia

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated

circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > elbow

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > genu

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > hip (joint) (disease) (bone)

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > joint

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > knee (joint)

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > shoulder (joint)

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > sternoclavicular joint

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > swelling, joint (see also category M01)

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > symphysis pubis

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > synovitis > articular

Tuberculosis, tubercular, tuberculous (calcification) (calcified) (caseous) (chromogenic acid-fast bacilli) (degeneration) (fibrocaseous) (fistula) (interstitial) (isolated circumscribed lesions) (necrosis) (parenchymatous) (ulcerative) > wrist (joint)

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We note that there were no Index entries specifically for ICD–10–CM diagnosis codes M71.061, M71.062, M71.069, M71.161, M71.162, and M71.169. Rather, there were Index entries at the subcategory levels of M71.06– and M71.16–. We found the following entries.

Index entry referring to M71.06–: (connective tissue) (embolic) (fistulous) (infective) (metastatic) (multiple) (pernicious) (pyogenic) (septic) > bursa > knee.
Index entry referring to M71.16–: Infective NEC > knee.

Our clinical advisors agreed that the results of our review of the ICD–10–CM Alphabetic Index support the addition of these ICD–10–CM diagnosis codes to MS–DRGs 485, 486, and 487 because the Index entries and/or the code descriptions clearly describe or include an infection that is specific to the knee.

Therefore, we are proposing to add the following ICD–10–CM diagnosis codes to the list of principal diagnosis codes for MS–DRGs 485, 486, and 487: A18.02; M01.X61; M01.X62; M01.X69; M71.061; M71.062; M71.069; M71.161; M71.162; and M71.169.

b. Neuromuscular Scoliosis

We received a request to add ICD–10–CM diagnosis codes describing neuromuscular scoliosis to the list of principal diagnosis codes for MS–DRGs 456, 457, and 458 (Spinal Fusion except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively). Excluding the ICD–10–CM diagnosis codes that address the cervical spine, the following ICD–10–CM diagnosis codes are used to describe neuromuscular scoliosis.

ICD–10–CM code	Code description
M41.40	Neuromuscular scoliosis, site unspecified.
M41.44	Neuromuscular scoliosis, thoracic region.
M41.45	Neuromuscular scoliosis, thoracolumbar region.
M41.46	Neuromuscular scoliosis, lumbar region.
M41.47	Neuromuscular scoliosis, lumbosacral region.

The requestor asserted that all levels of neuromuscular scoliosis, except cervical, should group to the non-cervical spinal fusion MS–DRGs for spinal curvature (MS–DRGs 456, 457, and 458). The requestor also noted that the current MS–DRG logic only groups cases reporting neuromuscular scoliosis to MS–DRGs 456, 457, and 458 when neuromuscular scoliosis is reported as a secondary diagnosis. The requestor contended that it would be rare for a diagnosis of neuromuscular scoliosis to be reported as a secondary diagnosis because there is not a ''code first'' note in the ICD–10–CM Tabular List of Diseases and Injuries indicating to ''code first'' the underlying cause. According to the requestor, when a diagnosis of neuromuscular scoliosis is the reason for an admission for non-cervical spinal fusion, neuromuscular scoliosis must be sequenced as the principal diagnosis because it is the chief condition responsible for the admission. However, this sequencing, which adheres to the ICD–10–CM Official Guidelines for Coding and Reporting, prevents the admission from grouping to the non-cervical spinal fusion MS–DRGs for spinal curvature caused by neuromuscular scoliosis.

We analyzed claims data from the September 2018 update of the FY 2018 MedPAR file for cases reporting any of the ICD–10–CM diagnosis codes describing neuromuscular scoliosis (as listed previously) as a principal diagnosis with a non-cervical spinal fusion, which are currently assigned to MS–DRGs 459 and 460 (Spinal Fusion except Cervical with MCC and without MCC, respectively). Our findings are shown in the following table.

MS–DRGs for Cases Involving Non-Cervical Spinal Fusion With Principal Diagnosis of Neuromuscular Scoliosis

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 459—All cases	3,903	8.6	$46,416
MS–DRG 459—Cases with principal diagnosis of neuromuscular scoliosis	3	15.3	95,745
MS–DRG 460—All cases	52,597	3.3	28,754
MS–DRG 460—Cases with principal diagnosis of neuromuscular scoliosis	8	4.3	71,406

The data reveal that there was a total of 56,500 cases in MS–DRGs 459 and 460. We found 3,903 cases reported in MS–DRG 459, with an average length of stay of 8.6 days and average costs of $46,416. Of these 3,903 cases, 3 reported a principal diagnosis code of neuromuscular scoliosis, with an average length of stay of 15.3 days and average costs of $95,745. We found a total of 52,597 cases in MS–DRG 460, with an average length of stay of 3.3 days and average costs of $28,754. Of these 52,597 cases, 8 cases reported a principal diagnosis code describing neuromuscular scoliosis, with an average length of stay of 4.3 days and average costs of $71,406. The data clearly demonstrate that the average costs and average length of stay for the small number of cases reporting a principal diagnosis of neuromuscular scoliosis are higher in comparison to all the cases in their assigned MS–DRG.

We also analyzed claims data for MS–DRGs 456, 457, and 458 (Spinal Fusion except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) to identify the spinal fusion cases reporting any of the ICD–10–CM codes describing neuromuscular scoliosis (as listed previously) as a secondary diagnosis. Our findings are shown in the following table.

MS–DRGS FOR CASES INVOLVING NON-CERVICAL SPINAL FUSION WITH SPINAL CURVATURE OR MALIGNANCY OR INFECTION OR EXTENSIVE FUSIONS WITH SECONDARY DIAGNOSIS OF NEUROMUSCULAR SCOLIOSIS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 456—All cases	1,344	12.0	$66,012
MS–DRG 456—Cases with secondary diagnosis of neuromuscular scoliosis	6	18.2	79,809
MS–DRG 457—All cases	3,654	6.2	47,577
MS–DRG 457—Cases with secondary diagnosis of neuromuscular scoliosis	12	4.5	31,646
MS–DRG 458—All cases	1,245	3.4	34,179
MS–DRG 458—Cases with secondary diagnosis of neuromuscular scoliosis	6	3.3	31,117

The data indicate that there were 1,344 cases reported in MS–DRG 456, with an average length of stay of 12 days and average costs of $66,012. Of these 1,344 cases, 6 cases reported a secondary diagnosis code describing neuromuscular scoliosis, with an average length of stay of 18.2 days and average costs of $79,809. We found a total of 3,654 cases in MS–DRG 457, with an average length of stay of 6.2 days and average costs of $47,577. Twelve of these 3,654 cases reported a secondary diagnosis code describing neuromuscular scoliosis, with an average length of stay of 4.5 days and average costs of $31,646. Finally, the 1,245 cases reported in MS–DRG 458 had an average length of stay of 3.4 days and average costs of $34,179. Of these 1,245 cases, 6 cases reported neuromuscular scoliosis as a secondary diagnosis, with an average length of stay of 3.3 days and average costs of $31,117.

We reviewed the ICD–10–CM Tabular List of Diseases for subcategory M41.4 and confirmed there is a ''Code also underlying condition'' note. We also reviewed the ICD–10–CM Official Guidelines for Coding and Reporting for the ''code also'' note at Section 1.A.12.b., which states: ''A 'code also' note instructs that two codes may be required to fully describe a condition, but this note does not provide sequencing direction.'' Our clinical advisors agree that the sequencing of the ICD–10–CM diagnosis codes is determined by which condition leads to the encounter and is responsible for the admission. They also note that there may be instances in which the underlying cause of the diagnosis of neuromuscular scoliosis is not treated or responsible for the admission.

As discussed earlier, our review of the claims data shows that a small number of cases reported neuromuscular scoliosis either as a principal diagnosis in MS–DRGs 459 and 460 or as a secondary diagnosis in MS–DRGs 456, 457, and 458. Our clinical advisors agree that while the volume of cases is small, the average costs and average length of stay for the cases reporting neuromuscular scoliosis as a principal diagnosis with a non-cervical spinal fusion currently grouping to MS–DRGs 459 and 460 are more aligned with the average costs and average length of stay for the cases reporting neuromuscular scoliosis as a secondary diagnosis with a non-cervical spinal fusion currently grouping to MS–DRGs 456, 457, and 458. Therefore, for the reasons described above, we are proposing to add the following ICD–10–CM codes describing neuromuscular scoliosis to the list of principal diagnosis codes for MS–DRGs 456, 457, and 458: M41.40; M41.44; M41.45; M41.46; and M41.47.

c. Secondary Scoliosis and Secondary Kyphosis

We received a request to add ICD–10–CM diagnosis codes describing secondary scoliosis and secondary kyphosis to the list of principal diagnoses for MS–DRGs 456, 457, and 458 (Spinal Fusion except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively). Excluding the ICD–10–CM diagnosis codes that address the cervical spine, the following ICD–10–CM diagnosis codes are used to describe secondary scoliosis.

ICD–10–CM code	Code description
M41.50	Other secondary scoliosis, site unspecified.
M41.54	Other secondary scoliosis, thoracic region.
M41.55	Other secondary scoliosis, thoracolumbar region.
M41.56	Other secondary scoliosis, lumbar region.
M41.57	Other secondary scoliosis, lumbosacral region.

Excluding the ICD–10–CM diagnosis codes that address the cervical spine, the following ICD–10–CM diagnosis codes are used to describe secondary kyphosis.

ICD–10–CM code	Code description
M40.10	Other secondary kyphosis, site unspecified.
M40.14	Other secondary kyphosis, thoracic region.
M40.15	Other secondary kyphosis, thoracolumbar region.

The requestor stated that generally in cases of diagnoses of secondary scoliosis or kyphosis, the underlying cause of the condition is not treated or is not responsible for the admission. If a patient is admitted for surgery to correct non-cervical spinal curvature, it is appropriate to sequence the diagnosis of secondary scoliosis or secondary kyphosis as principal diagnosis. However, reporting a diagnosis of secondary scoliosis or secondary

kyphosis as the principal diagnosis with a non-cervical spinal fusion procedure results in the case grouping to MS–DRG 459 or 460 (Spinal Fusion except Cervical with MCC and without MCC, respectively), instead of the spinal fusion with spinal curvature MS–DRGs 456, 457, and 458.

We analyzed claims data from the September 2018 update of the FY 2018 MedPAR file for MS–DRGs 459 and 460 to determine the number of cases reporting an ICD–10–CM diagnosis code describing secondary scoliosis or secondary kyphosis as the principal diagnosis. Our findings are shown in the following table.

MS–DRGs for Cases Involving Non-Cervical Spinal Fusion With a Principal Diagnosis of Secondary Scoliosis or Secondary Kyphosis

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 459—All cases	3,903	8.6	$46,416
MS–DRG 459—Cases with a principal diagnosis of secondary scoliosis	4	7.3	56,024
MS–DRG 459—Cases with a principal diagnosis of secondary kyphosis	4	5.8	41,883
MS–DRG 460—All cases	52,597	3.3	28,754
MS–DRG 460—Cases with a principal diagnosis of secondary scoliosis	34	3.6	34,424
MS–DRG 460—Cases with a principal diagnosis of secondary kyphosis	31	4.6	42,315

As shown in the table, we found a total of 3,903 cases in MS–DRG 459, with an average length of stay of 8.6 days and average costs of $46,416. Of these 3,903 cases, we found 4 cases that reported a principal diagnosis of secondary scoliosis, with an average length of stay of 7.3 days and average costs of $56,024. We also found 4 cases that reported a principal diagnosis of secondary kyphosis, with an average length of stay of 5.8 days and average costs of $41,883. For MS–DRG 460, we found a total of 52,597 cases with an average length of stay of 3.3 days and average costs of $28,754. Of these 52,597 cases, we found 34 cases that reported a principal diagnosis of secondary scoliosis, with an average length of stay of 3.6 days and average costs of $34,424. We found 31 cases that reported a principal diagnosis of secondary kyphosis in MS–DRG 460, with an average length of stay of 4.6 days and average costs of $42,315.

We also analyzed claims data for MS–DRGs 456, 457, and 458 to determine the number of cases reporting an ICD–10–CM diagnosis code describing secondary scoliosis or secondary kyphosis as a secondary diagnosis. Our findings are shown in the following table.

MS–DRGs for Cases Involving Non-Cervical Spinal Fusion With Spinal Curvature or Malignancy or Infection or Extensive Fusions With Secondary Diagnosis of Secondary Scoliosis or Secondary Kyphosis

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 456—All cases	1,344	12	$66,012
MS–DRG 456—Cases with a secondary diagnosis of secondary scoliosis	37	7.7	58,009
MS–DRG 456—Cases with a secondary diagnosis of secondary kyphosis	52	12	78,865
MS–DRG 457—All cases	3,654	6.2	47,577
MS–DRG 457—Cases with a secondary diagnosis of secondary scoliosis	187	4.9	37,655
MS–DRG 457—Cases with a secondary diagnosis of secondary kyphosis	114	5.2	37,357
MS–DRG 458—All cases	1,245	3.4	34,179
MS–DRG 458—Cases with a secondary diagnosis of secondary scoliosis	190	3.0	29,052
MS–DRG 458—Cases with a secondary diagnosis of secondary kyphosis	39	3.7	31,015

The data indicate that there were 1,344 cases in MS–DRG 456, with an average length of stay of 12 days and average costs of $66,012. Of these 1,344 cases, there were 37 cases that reported a secondary diagnosis of secondary scoliosis, with an average length of stay of 7.7 days and average costs of $58,009. There were also 52 cases in MS–DRG 456 reporting a secondary diagnosis of secondary kyphosis, with an average length of stay of 12 days and average costs of $78,865. In MS–DRG 457, there was a total of 3,654 cases, with an average length of stay of 6.2 days and average costs of $47,577. Of these 3,654 cases, there were 187 cases that reported secondary scoliosis as a secondary diagnosis, with an average length of stay of 4.9 days and average costs of $37,655. In MS–DRG 457, there were also 114 cases that reported a secondary diagnosis of secondary kyphosis, with an average length of stay of 5.2 days and average costs of $37,357. Finally, there was a total of 1,245 cases in MS–DRG 458, with an average length of stay of 3.4 days and average costs of $34,179. Of these 1,245 cases, there were 190 cases that reported a secondary diagnosis of secondary scoliosis, with an average length of stay of 3 days and average costs of $29,052. There were 39 cases in MS–DRG 458 that reported a secondary diagnosis of secondary kyphosis, with an average length of stay of 3.7 days and average costs of $31,015.

Our clinical advisors agree that the average length of stay and average costs for the small number of cases reporting secondary scoliosis or secondary kyphosis as a principal diagnosis with a non-cervical spinal fusion currently grouping to MS–DRGs 459 and 460 are generally more aligned with the average length of stay and average costs for the cases reporting secondary scoliosis or secondary kyphosis as a secondary diagnosis with a non-cervical spinal fusion currently grouping to MS–DRGs 456, 457, and 458. They also note that there may be instances in which the underlying cause of the diagnosis of secondary scoliosis or secondary kyphosis is not treated or responsible for the admission.

Therefore, for the reasons described above, we are proposing to add the following ICD–10–CM diagnosis codes describing secondary scoliosis and

secondary kyphosis to the list of principal diagnosis codes for MS–DRGs 456, 457, and 458: M40.10; M40.14; M40.15; M41.50; M41.54; M41.55; M41.56; and M41.57. During our review of MS–DRGs 456, 457, and 458, we found the following diagnosis codes that describe conditions involving the cervical region.

ICD–10–CM code	Code description
M40.03	Postural kyphosis, cervicothoracic region.
M40.202	Unspecified kyphosis, cervical region.
M40.203	Unspecified kyphosis, cervicothoracic region.
M40.292	Other kyphosis, cervical region.
M40.293	Other kyphosis, cervicothoracic region.
M41.02	Infantile idiopathic scoliosis, cervical region.
M41.03	Infantile idiopathic scoliosis, cervicothoracic region.
M41.112	Juvenile idiopathic scoliosis, cervical region.
M41.113	Juvenile idiopathic scoliosis, cervicothoracic region.
M41.122	Adolescent idiopathic scoliosis, cervical region.
M41.123	Adolescent idiopathic scoliosis, cervicothoracic region.
M41.22	Other idiopathic scoliosis, cervical region.
M41.23	Other idiopathic scoliosis, cervicothoracic region.
M41.82	Other forms of scoliosis, cervical region.
M41.83	Other forms of scoliosis, cervicothoracic region.
M42.01	Juvenile osteochondrosis of spine, occipito-atlanto-axial region.
M42.02	Juvenile osteochondrosis of spine, cervical region.
M42.03	Juvenile osteochondrosis of spine, cervicothoracic region.
M43.8X1	Other specified deforming dorsopathies, occipito-atlanto-axial region.
M43.8X2	Other specified deforming dorsopathies, cervical region.
M43.8X3	Other specified deforming dorsopathies, cervicothoracic region.
M46.21	Osteomyelitis of vertebra, occipito-atlanto-axial region.
M46.22	Osteomyelitis of vertebra, cervical region.
M46.23	Osteomyelitis of vertebra, cervicothoracic region.
M48.51XA	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, initial encounter for fracture.
M48.52XA	Collapsed vertebra, not elsewhere classified, cervical region, initial encounter for fracture.
M48.53XA	Collapsed vertebra, not elsewhere classified, cervicothoracic region, initial encounter for fracture.
M40.12	Other secondary kyphosis, cervical region.
M40.13	Other secondary kyphosis, cervicothoracic region.
M41.41	Neuromuscular scoliosis, occipito-atlanto-axial region.
M4.142	Neuromuscular scoliosis, cervical region.
M4143	Neuromuscular scoliosis, cervicothoracic region.
M41.52	Other secondary scoliosis, cervical region.
M41.53	Other secondary scoliosis, cervicothoracic region.

Our clinical advisors noted that because the diagnosis codes shown in the table above describe conditions involving the cervical region, they are not clinically appropriate for assignment to MS–DRGs 456, 457, and 458, which are defined by non-cervical spinal fusion procedures (with spinal curvature or malignancy or infection or extensive fusions). Therefore, our clinical advisors recommended that these codes be removed from the MS–DRG logic for these MS–DRGs. As such, we are proposing to remove the diagnosis codes that describe conditions involving the cervical region as shown in the table above from MS–DRGs 456, 457, and 458.

7. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): Extracorporeal Shock Wave Lithotripsy (ESWL)

We received two separate, but related requests to add ICD–10–CM diagnosis code N13.6 (Pyonephrosis) and ICD–10–CM diagnosis code T83.192A (Other mechanical complication of indwelling ureteral stent, initial encounter) to the list of principal diagnosis codes for MS–DRGs 691 and 692 (Urinary Stones with ESW Lithotripsy with CC/MCC and without CC/MCC, respectively) in MDC 11 so that cases are assigned more appropriately when an Extracorporeal Shock Wave Lithotripsy (ESWL) procedure is performed.

ICD–10–CM diagnosis code N13.6 currently groups to MS–DRGs 689 and 690 (Kidney and Urinary Tract Infections with MCC and without MCC, respectively) and ICD–10–CM diagnosis code T83.192A currently groups to MS–DRGs 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC/MCC, respectively).

The ICD–10–PCS procedure codes for identifying procedures involving ESWL are designated as non-O.R. procedures and are shown in the following table.

ICD–10–PCS code	Code description
0TF3XZZ	Fragmentation in right kidney pelvis, external approach.
0TF4XZZ	Fragmentation in left kidney pelvis, external approach.
OTF6XZZ	Fragmentation in right ureter, external approach.
OTF7XZZ	Fragmentation in left ureter, external approach.
OTFBXZZ	Fragmentation in bladder, external approach.
OTFCXZZ	Fragmentation in bladder neck, external approach.
OTFDXZZ	Fragmentation in urethra, external approach.

Pyonephrosis can be described as an infection of the kidney with pus in the upper collecting system which can progress to obstruction. Patients with an obstruction in the upper urinary tract due to urinary stones (calculi), tumors, fungus balls or ureteropelvic obstruction (UPJ) may also have a higher risk of developing pyonephrosis. If pyonephrosis is not recognized and treated promptly, it can result in serious complications, including fistulas, septic shock, irreversible damage to the kidneys, and death.

As noted above, the requestor recommended that ICD–10–CM diagnosis codes N13.6 and T83.192A be added to the list of principal diagnosis codes for MS–DRGs 691 and 692. There are currently four MS–DRGs that group cases for diagnoses involving urinary stones, which are subdivided to identify cases with and without an ESWL procedure: MS–DRGs 691 and 692 (Urinary Stones with ESW Lithotripsy with and without CC/MCC, respectively) and MS–DRGs 693 and 694 (Urinary Stones without ESW Lithotripsy with and without MCC, respectively).

The requestor stated that when patients who have been diagnosed with hydronephrosis secondary to renal and ureteral calculus obstruction undergo an ESWL procedure, ICD–10–CM diagnosis code N13.2 (Hydronephrosis with renal and ureteral calculous obstruction) is reported and groups to MS–DRGs 691 and 692. However, if a patient with a diagnosis of hydronephrosis has a urinary tract infection (UTI) in addition to a renal calculus obstruction and undergoes an ESWL procedure, ICD–10–CM diagnosis code N13.6 must be coded and reported as the principal diagnosis, which groups to MS–DRGs 689 and 690. The requestor stated that ICD–10–CM diagnosis code N13.6 should be grouped to MS–DRGs 691 and 692 when reported as a principal diagnosis because this grouping will more appropriately reflect resource consumption for patients who undergo an ESWL procedure for obstructive urinary calculi, while also receiving treatment for urinary tract infections.

With regard to ICD–10–CM diagnosis code T83.192A, the requestor believed that when an ESWL procedure is performed for the treatment of calcifications within and around an indwelling ureteral stent, it is comparable to an ESWL procedure performed for the treatment of urinary calculi. Therefore, the requestor recommended adding ICD–10–CM diagnosis code T83.192A to MS–DRGs 691 and 692 when reported as a principal diagnosis and an ESWL procedure is also reported on the claim.

To analyze these separate, but related requests, we first reviewed the reporting of ICD–10–CM diagnosis code N13.6 within the ICD–10–CM classification. ICD–10–CM diagnosis code N13.6 is to be assigned for conditions identified in the code range N13.0–N13.5 with infection. (Codes in this range describe hydronephrosis with obstruction.) Infection may be documented by the patient's provider as urinary tract infection (UTI) or as specific as acute pyelonephritis. We agree with the requestor that if a patient with a diagnosis of hydronephrosis has a urinary tract infection (UTI) in addition to a renal calculus obstruction and undergoes an ESWL procedure, ICD–10–CM diagnosis code N13.6 must be coded and reported as the principal diagnosis, which groups to MS–DRGs 689 and 690. In this case scenario, the ESWL procedure is designated as a non-O.R. procedure and does not impact the MS–DRG assignment when reported with ICD–10–CM diagnosis code N13.6.

The ICD–10–CM classification instructs that when both a urinary obstruction and a genitourinary infection co-exist, the correct code assignment for reporting is ICD–10–CM diagnosis code N13.6, which is appropriately grouped to MS–DRGs 689 and 690 (Kidney and Urinary Tract Infections with MCC and without MCC, respectively) because it describes a type of urinary tract infection. Therefore, in response to the requestor's suggestion that ICD–10–CM diagnosis code N13.6 be grouped to MS–DRGs 691 and 692 when reported as a principal diagnosis to more appropriately reflect resource consumption for patients who undergo an ESWL procedure for obstructive urinary calculi while also receiving treatment for urinary tract infections, we note that the ICD–10–CM classification provides instruction to identify the conditions reported with ICD–10–CM diagnosis code N13.6 as an infection, and not as urinary stones. Our clinical advisors agree with this classification and the corresponding MS–DRG assignment for diagnosis code N13.6. In addition, our clinical advisors noted that an ESWL procedure is a non-O.R. procedure and they do not believe that this procedure is a valid indicator of resource consumption for cases that involve an infection and obstruction. Our clinical advisors believe that the resources used for a case that involves an infection and an obstruction are clinically distinct from the cases that involve an obstruction only in the course of treatment. Therefore, our clinical advisors do not agree with the request to add ICD–10–CM diagnosis code N13.6 to the list of principal diagnoses for MS–DRGs 691 and 692.

We also performed various analyses of claims data to evaluate this request. We analyzed claims data from the September 2018 update of the FY 2018 MedPAR file for MS–DRGs 689 and 690 to identify cases reporting ICD–10–CM diagnosis code N13.6 as the principal diagnosis with and without an ESWL procedure. Our findings are reflected in the table below.

KIDNEY AND URINARY TRACT INFECTIONS WITH PRINCIPAL DIAGNOSIS OF PYONEPHROSIS WITH AND WITHOUT ESWL

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 689—All cases	68,020	4.8	$7,873
MS–DRG 689—Cases with principal diagnosis of pyonephrosis	1,024	6.1	13,809
MS–DRG 689—Cases with principal diagnosis of pyonephrosis with ESWL	6	14.2	45,489
MS–DRG 690—All cases	131,999	3.5	5,692
MS–DRG 690—Cases with principal diagnosis of pyonephrosis	4,625	3.6	5,483
MS–DRG 690—Cases with principal diagnosis of pyonephrosis with ESWL	24	4.8	14,837

For MS–DRG 689, we found a total of 68,020 cases with an average length of stay of 4.8 days and average costs of $7,873. Of those 68,020 cases, we found 1,024 cases reporting pyonephrosis (ICD–10–CM diagnosis code N13.6) as a principal diagnosis with an average length of stay of 6.1 days and average costs of $13,809. Of those 1,024 cases reporting pyonephrosis (ICD–10–CM diagnosis code N13.6) as a principal diagnosis, there were 6 cases that also reported an ESWL procedure with an average length of stay of 14.2 days and average costs of $45,489. For MS–DRG

690, we found a total of 131,999 cases with an average length of stay of 3.5 days and average costs of $5,692. Of those 131,999 cases, we found 4,625 cases reporting pyonephrosis (ICD–10–CM diagnosis code N13.6) as a principal diagnosis with an average length of stay of 3.6 days and average costs of $5,483. Of those 4,625 cases reporting pyonephrosis (ICD–10–CM diagnosis code N13.6) as a principal diagnosis, there were 24 cases that also reported an ESWL procedure with an average length of stay of 4.8 days and average costs of $14,837.

The data indicate that the 1,024 cases reporting pyonephrosis (ICD–10–CM diagnosis code N13.6) as a principal diagnosis in MS–DRG 689 have a longer average length of stay (6.1 days versus 4.8 days) and higher average costs ($13,809 versus $7,873) compared to all the cases in MS–DRG 689. The data also indicate that the 6 cases reporting pyonephrosis (ICD–10–CM diagnosis code N13.6) as a principal diagnosis that also reported an ESWL procedure have a longer average length of stay (14.2 days versus 4.8 days) and higher average costs ($45,489 versus $7,873) in comparison to all the cases in MS–DRG 689. We found similar results for cases reporting pyonephrosis (ICD–10–CM diagnosis code N13.6) as a principal diagnosis with an ESWL procedure in MS–DRG 690, where the average length of stay was slightly longer (4.8 days versus 3.5 days) and the average costs were higher ($14,837 versus $5,692).

We then conducted further analysis for the six cases in MS–DRG 689 that reported a principal diagnosis of pyonephrosis with ESWL to determine what factors may be contributing to the longer lengths of stay and higher average costs. Specifically, we analyzed the MCC conditions that were reported across the six cases. Our findings are shown in the table below.

SECONDARY DIAGNOSIS MCC CONDITIONS REPORTED IN MS–DRG 689 WITH PRINCIPAL DIAGNOSIS OF PYONEPHROSIS WITH ESWL

ICD–10–CM code	Description	Number of times reported	Average length of stay	Average costs
A41.9	Sepsis, unspecified organism	2	26.5	96,525
G82.50	Quadriplegia, unspecified	1	7	13,782
I50.23	Acute on chronic systolic (congestive) heart failure	1	7	13,304
J96. 01	Acute respiratory failure with hypoxia	1	7	13,304
K66.1	Hemoperitoneum	1	10	26,314
L89.153	Pressure ulcer of sacral region, stage 3	1	8	26,487
R57.1	Hypovolemic shock	1	10	26,314
Total		8	12.8	39,069

We found seven secondary diagnosis MCC conditions reported among the six cases in MS–DRG 689 that had a principal diagnosis of pyonephrosis with ESWL. These MCC conditions appear to have contributed to the longer lengths of stay and higher average costs for those six cases. As shown in the table above, the overall average length of stay for the cases reporting these conditions is 12.8 days with average costs of $39,069, which is consistent with the average length of stay of 14.2 days and average costs of $45,489 for the cases in MS–DRG 689 that had a principal diagnosis of pyonephrosis with ESWL.

We then analyzed the 24 cases in MS–DRG 690 that reported a principal diagnosis of pyonephrosis with ESWL to determine what factors may be contributing to the longer lengths of stay and higher average costs. Specifically, we analyzed the CC conditions that were reported across the 24 cases. Our findings are shown in the table below.

SECONDARY DIAGNOSIS CC CONDITIONS REPORTED IN MS–DRG 690 WITH PRINCIPAL DIAGNOSIS OF PYONEPHROSIS WITH ESWL

ICD–10–CM code	Description	Number of times reported	Average length of stay	Average costs
B37.0	Candidal stomatitis	2	9.5	$18,895
B37.49	Other urogenital candidiasis	2	7.5	30,458
C79.89	Secondary malignant neoplasm of other specified sites	1	3	5,882
E22.2	Syndrome of inappropriate secretion of antidiuretic hormone	1	2	5,979
E44.0	Moderate protein-calorie malnutrition	1	6	9,027
E46	Unspecified protein-calorie malnutrition	2	5.5	8,704
E87.0	Hyperosmolality and hypernatremia	1	6	9,027
E87.1	Hypo-osmolality and hyponatremia	1	5	12,339
F11.20	Opioid dependence, uncomplicated	1	1	8,209
F33.1	Major depressive disorder, recurrent, moderate	1	12	55,034
G81.94	Hemiplegia, unspecified affecting left nondominant side	3	9.3	25,390
G82.20	Paraplegia, unspecified	1	10	15,142
G93.40	Encephalopathy, unspecified	2	7	10,277
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney dis.	1	4	12,348
I48.1	Persistent atrial fibrillation	1	12	55,034
I50.22	Chronic systolic (congestive) heart failure	1	12	55,034
I50.32	Chronic diastolic (congestive) heart failure	2	3.5	9,115
I69.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side.	1	3	4,845

SECONDARY DIAGNOSIS CC CONDITIONS REPORTED IN MS–DRG 690 WITH PRINCIPAL DIAGNOSIS OF PYONEPHROSIS WITH ESWL—Continued

ICD–10–CM code	Description	Number of times reported	Average length of stay	Average costs
I69.859	Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side.	1	4	18,160
I97.791	Other intraoperative cardiac functional disturbances during other surgery	1	8	8,114
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection.	1	11	25,641
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation	2	5	11,283
J96.10	Chronic respiratory failure, unspecified whether with hypoxia or hypercapnia.	1	12	55,034
J96.11	Chronic respiratory failure with hypoxia	2	7	15,243
K57.92	Diverticulitis of intestine, part unspecified, without perforation or abscess without bleeding.	1	8	12,150
N12	Tubulo-interstitial nephritis, not specified as acute or chronic	1	11	25,641
N13.8	Other obstructive and reflux uropathy	1	5	32,854
N17.9	Acute kidney failure, unspecified	1	2	21,329
N20.1	Calculus of ureter	1	10	15,142
N20.2	Calculus of kidney with calculus of ureter	1	6	9,027
R44.3	Hallucinations, unspecified	1	2	21,329
R47.01	Aphasia	1	4	10,161
R78.81	Bacteremia	1	11	4,849
S37.012A	Minor contusion of left kidney, initial encounter	1	2	21,329
T83.511A	Infection and inflammatory reaction due to indwelling urethral catheter, initial encounter.	1	10	15,142
Z68.1	Body mass index (BMI) 19.9 or less, adult	2	4.5	10,040
Z68.43	Body mass index (BMI) 50–59.9, adult	1	3	6,145
Total		47	6.6	18,173

We found 37 secondary diagnosis CC conditions reported among the 24 cases in MS–DRG 690 that had a principal diagnosis of pyonephrosis with ESWL. These CC conditions appear to have contributed to the longer length of stay and higher average costs for those 24 cases. As shown in the table above, the overall average length of stay for the cases reporting these conditions is 6.6 days with average costs of $18,173, which is higher, although comparable, to the average length of stay of 4.8 days and average costs of $14,837 for the cases in MS–DRG 690 that had a principal diagnosis of pyonephrosis with ESWL. We note that it appears that 1 of the 24 cases had at least 4 secondary diagnosis CC conditions (F33.1, I48.1, I50.22, and J96.10) with an average length of stay of 12 days and average costs of $55,034, which we believe contributed greatly overall to the longer length of stay and higher average costs for those secondary diagnosis CC conditions reported among the 24 cases.

Our clinical advisors agree that the resource consumption for the 6 cases in MS–DRG 689 and the 24 cases in MS–DRG 690 that reported a principal diagnosis of pyonephrosis with ESWL cannot be directly attributed to ESWL and believe that it is the secondary diagnosis MCC and CC conditions that are the major contributing factors to the longer average length of stay and higher average costs for these cases.

We also analyzed claims data for MS–DRGs 691 and 692 (Urinary Stones with ESW Lithotripsy with CC/MCC and without CC/MCC, respectively) and MS–DRGs 693 and 694 (Urinary Stones without ESW Lithotripsy with MCC and without MCC, respectively) to identify claims reporting pyonephrosis (ICD–10–CM diagnosis code N13.6) as a secondary diagnosis. Our findings are shown in the following table.

MS–DRGS FOR URINARY STONES WITH SECONDARY DIAGNOSIS OF PYONEPHROSIS WITH AND WITHOUT ESWL

MS–DRG	Number of times reported	Average length of stay	Average costs
MS–DRG 691—All cases	140	3.9	$11,997
MS–DRG 691—Cases with secondary diagnosis of pyonephrosis and ESWL	3	8	24,280
MS–DRG 692—All cases	124	2.1	8,326
MS–DRG 693—All cases	1,315	5.1	9,668
MS–DRG 693—Cases with secondary diagnosis of pyonephrosis	16	5.5	9,962
MS–DRG 694—All cases	7,240	2.7	5,263
MS–DRG 694—Cases with secondary diagnosis of pyonephrosis	89	3.5	6,678

As shown in the table above, in MS–DRG 691, there was a total of 140 cases with an average length of stay of 3.9 days and average costs of $11,997. Of those 140 cases, there were 3 cases that reported pyonephrosis as a secondary diagnosis and an ESWL procedure with an average length of stay of 8.0 days and average costs of $24,280. There was a total of 124 cases found in MS–DRG 692 with an average length of stay of 2.1 days and average costs of $8,326. There were no cases in MS–DRG 692 that reported pyonephrosis as a secondary diagnosis with an ESWL procedure. For MS–DRG 693, there was a total of 1,315 cases with an average length of stay of 5.1 days and average costs of $9,668. Of

those 1,315 cases, there were 16 cases reporting pyonephrosis as a secondary diagnosis with an average length of stay of 5.5 days and average costs of $9,962. For MS–DRG 694, there was a total of 7,240 cases with an average length of stay of 2.7 days and average costs of $5,263. Of those 7,240 cases, there were 89 cases reporting pyonephrosis as a secondary diagnosis with an average length of stay of 3.5 days and average costs of $6,678.

Similar to the process described above, we then conducted further analysis for the three cases in MS–DRG 691 that reported a secondary diagnosis of pyonephrosis with ESWL to determine what factors may be contributing to the longer lengths of stay and higher average costs. Specifically, we analyzed what other MCC and CC conditions were reported across the three cases. We found no other MCC conditions reported for those three cases. Our findings for the CC conditions reported for those three cases are shown in the table below.

SECONDARY DIAGNOSIS CC CONDITIONS REPORTED IN MS–DRG 691

ICD–10–CM code	Description	Number of times reported	Average length of stay	Average costs
E44.0	Moderate protein-calorie malnutrition	1	15	$52,384
J96.10	Chronic respiratory failure, unspecified whether with hypoxia or hypercapnia.	1	7	15,110
N13.6	Pyonephrosis	2	8.5	28,865
N17.9	Acute kidney failure, unspecified	1	2	5,346
N39.0	Urinary tract infection, site not specified	1	2	5,346
Q79.6	Ehlers-Danlos syndrome	1	2	5,346
Total		7	6.4	20,181

We found six secondary diagnosis CC conditions reported among the three cases in MS–DRG 691 that had a secondary diagnosis of pyonephrosis with ESWL. These CC conditions appear to have contributed to the longer lengths of stay and higher average costs for those three cases. As shown in the table above, the overall average length of stay for the cases reporting these conditions is 6.4 days with average costs of $20,181, which is more consistent with the average length of stay of 8.0 days and average costs of $24,280 for the cases in MS–DRG 691 that had a secondary diagnosis of pyonephrosis with ESWL.

Our clinical advisors believe that the resource consumption for those three cases cannot be directly attributed to ESWL and that it is the secondary diagnosis CC conditions reported in addition to pyonephrosis, which is also designated as a CC condition, that are the major contributing factors for the longer average lengths of stay and higher average costs for these cases in MS–DRG 691.

We did not conduct further analysis for the 16 cases in MS–DRG 693 or the 89 cases in MS–DRG 694 that reported a secondary diagnosis of pyonephrosis because MS–DRGs 693 and 694 do not include ESWL procedures and the average length of stay and average costs for those cases were consistent with the data findings for all of the cases in their assigned MS–DRG.

As discussed earlier in this section, the requestor suggested that ICD–10–CM diagnosis code N13.6 should be grouped to MS–DRGs 691 and 692 when reported as a principal diagnosis because this grouping will more appropriately reflect resource consumption for patients who undergo an ESWL procedure for obstructive urinary calculi, while also receiving treatment for urinary tract infections. However, based on the results of the data analysis and input from our clinical advisors, we believe that cases for which ICD–10–CM diagnosis code N13.6 was reported as a principal diagnosis or as a secondary diagnosis with an ESWL procedure should not be utilized as an indicator for increased utilization of resources based on the performance of an ESWL procedure. Rather, we believe that the resource consumption is more likely the result of secondary diagnosis CC and/or MCC diagnosis codes.

With respect to the requestor's concern that cases reporting ICD–10–CM diagnosis code T83.192A (Other mechanical complication of indwelling ureteral stent, initial encounter) and an ESWL procedure are not appropriately assigned and should be added to the list of principal diagnoses for MS–DRGs 691 and 692 (Urinary Stones with ESW Lithotripsy with CC/MCC and without CC/MCC, respectively), our clinical advisors note that ICD–10–CM diagnosis code T83.192A is not necessarily indicative of a patient having urinary stones. As such, they do not support adding ICD–10–CM diagnosis code T83.192A to the list of principal diagnosis codes for MS–DRGs 691 and 692.

We analyzed claims data to identify cases reporting ICD–10–CM diagnosis code T83.192A as a principal diagnosis with ESWL in MS–DRGs 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC/MCC, respectively). Our findings are shown in the following table.

MS–DRGS FOR OTHER KIDNEY AND URINARY TRACT DIAGNOSES WITH PRINCIPAL DIAGNOSIS OF OTHER MECHANICAL COMPLICATIONS OF INDWELLING URETERAL STENT WITH ESWL

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 698—All cases	56,803	6.1	$11,220
MS–DRG 698—Cases with diagnosis code T83.192A reported as principal diagnosis	35	7.1	14,574
MS–DRG 699—All cases	33,693	4.2	7,348
MS–DRG 699—Cases with diagnosis code T83.192A reported as principal diagnosis	63	4.1	7,652
MS–DRG 699—Cases with diagnosis code T83.192A reported as principal diagnosis with ESWL	1	3	7,986

MS–DRGS FOR OTHER KIDNEY AND URINARY TRACT DIAGNOSES WITH PRINCIPAL DIAGNOSIS OF OTHER MECHANICAL COMPLICATIONS OF INDWELLING URETERAL STENT WITH ESWL—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 700—All cases	3,719	3	5,356

For MS–DRG 698, there was a total of 56,803 cases reported, with an average length of stay of 6.1 days and average costs of $11,220. Of these 56,803 cases, 35 cases reported ICD–10–CM diagnosis code T83.192A as the principal diagnosis, with an average length of stay of 7.1 days and average costs of $14,574. There were no cases that reported an ESWL procedure with ICD–10–CM diagnosis code T83.192A as the principal diagnosis in MS–DRG 698. For MS–DRG 699, there was a total of 33,693 cases reported, with an average length of stay of 4.2 days and average costs of $7,348. Of the 33,693 cases in MS–DRG 699, there were 63 cases that reported ICD–10–CM diagnosis code T83.192A as the principal diagnosis, with an average length of stay of 4.1 days and average costs of $7,652. There was only 1 case in MS–DRG 699 that reported ICD–10–CM diagnosis code T83.192A as the principal diagnosis with an ESWL procedure, with an average length of stay of 3 days and average costs of $7,986. For MS–DRG 700, there was a total of 3,719 cases reported, with an average length of stay of 3 days and average costs of $5,356. There were no cases that reported ICD–10–CM diagnosis code T83.192A as the principal diagnosis in MS–DRG 700. Of the 98 cases in MS–DRGs 698 and 699 that reported a principal diagnosis of other mechanical complication of indwelling ureteral stent (diagnosis code T83.192A), only 1 case also reported an ESWL procedure. Based on the results of our data analysis and input from our clinical advisors, we are not proposing to add ICD–10–CM diagnosis code T83.192A to the list of principal diagnosis codes for MS–DRGs 691 and 692.

In connection with these requests, our clinical advisors recommended that we evaluate the frequency with which ESWL is reported in the inpatient setting across all the MS–DRGs. Therefore, we also analyzed claims data from the September 2018 update of the FY 2018 MedPAR file to identify the other MS–DRGs to which claims reporting an ESWL procedure were reported. Our findings are shown in the following table.

MS–DRGs	MS–DRG description
654	Major Bladder Procedures with CC.
657	Kidney and Ureter Procedures for Neoplasm with CC.
659, 660, 661	Kidney and Ureter Procedures for Non-Neoplasm with MCC, with CC, without CC/MCC, respectively.
662, 663	Minor Bladder Procedures with MCC and with CC, respectively.
665, 666	Prostatectomy with MCC and with CC, respectively.
668, 669, 670	Transurethral Procedures with MCC, with CC, and without CC/MCC, respectively.
671	Urethral Procedures with CC/MCC.
682, 683	Renal Failure with MCC and with CC, respectively.
689, 690	Kidney and Urinary Tract Infections with MCC and without MCC, respectively.
691, 692	Urinary Stones with ESW Lithotripsy with CC/MCC and without CC/MCC, respectively.
696	Kidney and Urinary Tract Signs and Symptoms without MCC.
698, 699, 700	Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC/MCC, respectively.
982	Extensive O.R. Procedure Unrelated to Principal Diagnosis with CC.

Our findings with respect to the cases reporting an ESWL procedure in each of these MS–DRGs, as compared to all cases in the applicable MS–DRG, are shown in the table below.

MS–DRG	Number of times reported	Average length of stay	Average costs
MS–DRG 654—All cases	3,838	6.7	$19,805
MS–DRG 654—Cases reporting ESWL	1	5	9,102
MS–DRG 657—All cases	7,242	4.1	14,047
MS–DRG 657—Cases reporting ESWL	2	2	19,021
MS–DRG 659—All cases	7,761	8.1	18,717
MS–DRG 659—Cases reporting ESWL	71	11.1	26,366
MS–DRG 660—All cases	17,617	4.1	10,292
MS–DRG 660—Cases reporting ESWL	193	4	13,627
MS–DRG 661—All cases	12,434	2.3	7,997
MS–DRG 661—Cases reporting ESWL	154	2.7	12,639
MS–DRG 662—All cases	614	10.2	23,110
MS–DRG 662—Cases reporting ESWL	1	22	57,520
MS–DRG 663—All cases	1,349	5	11,213
MS–DRG 663—Cases reporting ESWL	2	3.5	15,870
MS–DRG 665—All cases	589	9.4	21,328
MS–DRG 665—Cases reporting ESWL	2	16.5	17,710
MS–DRG 666—All cases	1,517	5.6	13,060
MS–DRG 666—Cases reporting ESWL	2	9.5	16,521
MS–DRG 668—All cases	2,065	9	20,229

MS–DRG	Number of times reported	Average length of stay	Average costs
MS–DRG 668—Cases reporting ESWL	1	4	19,383
MS–DRG 669—All cases	5,259	4.9	11,217
MS–DRG 669—Cases reporting ESWL	5	2.4	13,006
MS–DRG 670—All cases	1,707	2.6	7,177
MS–DRG 670—Cases reporting ESWL	5	3	18,416
MS–DRG 671—All cases	367	6.4	13,519
MS–DRG 671—Cases reporting ESWL	1	3	29,731
MS–DRG 682—All cases	97,347	5.7	10,384
MS–DRG 682—Cases reporting ESWL	5	10	26,773
MS–DRG 683—All cases	132,206	3.9	6,450
MS–DRG 683—Cases reporting ESWL	4	13.3	19,706
MS–DRG 689—All cases	68,020	4.8	7,873
MS–DRG 689—Cases reporting ESWL	11	13.3	35,510
MS–DRG 690—All cases	131,999	3.5	5,692
MS–DRG 690—Cases reporting ESWL	39	4.9	13,567
MS–DRG 691—All cases	140	3.9	11,997
MS–DRG 691—Cases reporting ESWL	140	3.9	11,997
MS–DRG 692—All cases	124	2.1	8,326
MS–DRG 692—Cases reporting ESWL	124	2.1	8,326
MS–DRG 696—All cases	5,933	2.9	4,938
MS–DRG 696—Cases reporting ESWL	2	2.5	6,238
MS–DRG 698—All cases	56,803	6.1	11,220
MS–DRG 698—Cases reporting ESWL	18	9.2	27,818
MS–DRG 699—All cases	33,693	4.2	7,348
MS–DRG 699—Cases reporting ESWL	9	4.4	10,986
MS–DRG 700—All cases	3,719	3	5,356
MS–DRG 700—Cases reporting ESWL	1	1	7,580
MS–DRG 982—All cases	16,834	6.3	16,939
MS–DRG 982—Cases reporting ESWL	2	11	74,751

Our data analysis indicates that, generally, the subset of cases reporting an ESWL procedure appear to have a longer average length of stay and higher average costs when compared to all the cases in their assigned MS–DRG. However, we note that this same subset of cases also reported at least one O.R. procedure and/or diagnosis designated as a CC or an MCC, which our clinical advisors believe are contributing factors to the longer average lengths of stay and higher average costs, with the exception of the case assigned to MS–DRG 700, which is a medical MS–DRG and has no CC or MCC conditions in the logic. Therefore, our clinical advisors do not believe that cases reporting an ESWL procedure should be considered as an indication of increased resource consumption for inpatient hospitalizations.

Our clinical advisors also suggested that we evaluate the reporting of ESWL procedures in the inpatient setting over the past few years. We analyzed claims data for MS–DRGs 691 and 692 from the FY 2012 through the FY 2016 MedPAR files, which were used in our analysis of claims data for MS–DRG reclassification requests effective for FY 2014 through FY 2018. We note that the analysis findings shown in the following table reflect ICD–9–CM, ICD–10–CM and ICD–10–PCS coded claims data.

MS–DRG	FY 2014 (version 31)			FY 2015 (version 32)			FY 2016 (version 33)			FY 2017 (version 34)			FY 2018 (version 35)		
	Number of cases	Average length of stay	Average costs	Number of cases	Average length of stay	Average costs	Number of cases	Average length of stay	Average costs	Number of cases	Average length of stay	Average costs	Number of cases	Average length of stay	Average costs
MS–DRG 691—Urinary Stones with ESW Lithotripsy w CC/MCC	898	3.77	$10,274	832	3.81	$11,141	812	3.72	$11,534	750	4.06	$11,907	448	3.4	$11,502
MS–DRG 692—Urinary Stones with ESW Lithotripsy without CC/MCC	231	2.02	7,292	197	2.14	8,041	133	2.32	9,273	103	2.39	9,398	61	2.3	8,702

The data show a steady decline in the number of cases reporting urinary stones with an ESWL procedure for the past 5 years. As previously noted, the total number of cases reporting urinary stones with an ESWL procedure for MS–DRGs 691 and 692 based on our analysis of the September 2018 update of the FY 2018 MedPAR file was 264, which again is a decline from the prior year's figures. As discussed throughout this section, an ESWL procedure is a non-O.R. procedure which currently groups to medical MS–DRGs 691 and 692. Therefore, because an ESWL procedure is a non-O.R. procedure and due to decreased usage of this procedure in the inpatient setting for the treatment of urinary stones, our clinical advisors believe that there is no longer a clinical reason to subdivide the MS–DRGs for urinary stones (MS–DRGs 691, 692, 693, and 694) based on ESWL procedures.

Therefore, we are proposing to delete MS–DRGs 691 and 692 and to revise the titles for MS–DRGs 693 and 694 from ''Urinary Stones without ESW Lithotripsy with MCC'' and ''Urinary Stones without ESW Lithotripsy without MCC'', respectively to ''Urinary Stones with MCC'' and ''Urinary Stones without MCC'', respectively.

8. MDC 12 (Diseases and Disorders of the Male Reproductive System): Diagnostic Imaging of Male Anatomy

We received a request to review four ICD–10–CM diagnosis codes describing

body parts associated with male anatomy that are currently assigned to MDC 5 (Diseases and Disorders of the Circulatory System) in MS–DRGs 302 and 303 (Atherosclerosis with MCC and Atherosclerosis without MCC, respectively). The four codes are listed in the following table.

ICD–10–CM code	Code description
R93.811	Abnormal radiologic findings on diagnostic imaging of right testicle.
R93.812	Abnormal radiologic findings on diagnostic imaging of left testicle.
R93.813	Abnormal radiologic findings on diagnostic imaging of testicles, bilateral.
R93.819	Abnormal radiologic findings on diagnostic imaging of unspecified testicle.

The requestor recommended that the four diagnosis codes shown in the table above be considered for assignment to MDC 12 (Diseases and Disorders of the Male Reproductive System), consistent with other diagnosis codes that include the male anatomy. However, the requestor did not suggest a specific MS–DRG assignment within MDC 12.

We examined claims data from the September 2018 update of the FY 2018 MedPAR file for MS–DRGs 302 and 303 to identify any cases reporting a diagnosis code for abnormal radiologic findings on diagnostic imaging of the testicles. We did not find any such cases.

Our clinical advisors reviewed this request and determined that the assignment of diagnosis codes R93.811, R93.812, R93.813, and R93.819 to MDC 5 in MS–DRGs 302 and 303 was a result of replication from ICD–9–CM diagnosis code 793.2 (Nonspecific (abnormal) findings on radiological and other examination of other intrathoracic organs) which was assigned to those MS–DRGs. Therefore, our clinical advisors support reassignment of these codes to MDC 12. Our clinical advisors agree that this reassignment is clinically appropriate because these diagnosis codes are specific to the male anatomy, consistent with other diagnosis codes in MDC 12 that include the male anatomy. Specifically, our clinical advisors suggest reassignment of the four diagnosis codes to MS–DRGs 729 and 730 (Other Male Reproductive System Diagnoses with CC/MCC and without CC/MCC, respectively). Therefore, we are proposing to reassign ICD–10–CM diagnosis codes R93.811, R93.812, R93.813, and R93.819 from MDC 5 in MS–DRGs 302 and 303 to MDC 12 in MS–DRGs 729 and 730.

9. MDC 14 (Pregnancy, Childbirth and the Puerperium): Proposed Reassignment of Diagnosis Code O99.89

We received a request to review the MS–DRG assignment for cases reporting ICD–10–CM diagnosis code O99.89 (Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium). The requestor stated that it is experiencing MS–DRG shifts to MS–DRG 769 (Postpartum and Post Abortion Diagnoses with O.R. Procedure) as a result of the new obstetric MS–DRG logic when ICD–10–CM diagnosis code O99.89 is reported as a principal diagnosis in the absence of a delivery code on the claim (to indicate the patient delivered during that hospitalization), or when there is no other secondary diagnosis code on the claim indicating that the patient is in the postpartum period. According to the requestor, claims reporting ICD–10–CM diagnosis code O99.89 as a principal diagnosis for conditions described as occurring during the antepartum period that are reported with an O.R. procedure are grouping to MS–DRG 769. In the example provided by the requestor, ICD–10–CM diagnosis code O99.89 was reported as the principal diagnosis, with ICD–10–CM diagnosis codes N13.2 (Hydronephrosis with renal and ureteral calculous obstruction) and Z3A.25 (25 weeks of gestation of pregnancy) reported as secondary diagnoses with ICD–10–PCS procedure code 0T68DZ (Dilation of right ureter with intraluminal device, endoscopic approach), resulting in assignment to MS–DRG 769. The requestor noted that, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41212), we stated ''If there was not a principal diagnosis of abortion reported on the claim, the logic asks if there was a principal diagnosis of an antepartum condition reported on the claim. If yes, the logic then asks if there was an O.R. procedure reported on the claim. If yes, the logic assigns the case to one of the proposed new MS–DRGs 817, 818, or 819.'' In the requestor's example, there were not any codes reported to indicate that the patient was in the postpartum period, nor was there a delivery code reported on the claim. Therefore, the requestor suggested that a more appropriate assignment for ICD–10–CM diagnosis code O99.89 may be MS–DRGs 817, 818, and 819 (Other Antepartum Diagnoses with O.R. Procedure with MCC, with CC and without CC/MCC, respectively).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41202 through 41216), we finalized our proposal to restructure the MS–DRGs within MDC 14 (Pregnancy, Childbirth and the Puerperium) which established new concepts for the GROUPER logic. As a result of the modifications made, ICD–10–CM diagnosis code O99.89 was classified as a postpartum condition and is currently assigned to MS–DRG 769 (Postpartum and Post Abortion Diagnoses with O.R. Procedure) and MS–DRG 776 (Postpartum and Post Abortion Diagnoses without O.R. Procedure) under the Version 36 ICD–10 MS–DRGs. As also discussed and displayed in Diagram 2 in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41212 through 41213), the logic asks if there was a principal diagnosis of a postpartum condition reported on the claim. If yes, the logic then asks if there was an O.R. procedure reported on the claim. If yes, the logic assigns the case to MS–DRG 769. If no, the logic assigns the case to MS–DRG 776. Therefore, the MS–DRG assignment for the example provided by the requestor is grouping accurately according to the current GROUPER logic.

We analyzed claims data from the September 2018 update of the FY 2018 MedPAR file for cases reporting diagnosis code O99.89 in MS–DRGs 769 and 776 as a principal diagnosis or as a secondary diagnosis. Our findings are shown in the following table.

POSTPARTUM MS–DRGS WITH PRINCIPAL OR SECONDARY DIAGNOSIS OF OTHER SPECIFIED DISEASES AND CONDITIONS COMPLICATING PREGNANCY, CHILDBIRTH AND THE PUERPERIUM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 769—All cases	91	4.3	$11,015
MS–DRG 769—Cases reporting diagnosis code O99.89 as principal diagnosis	7	5.6	19,059
MS–DRG 769—Cases reporting diagnosis code O99.89 as secondary diagnosis	61	12.1	41,717
MS–DRG 776—All cases	560	3.1	5,332
MS–DRG 776—Cases reporting diagnosis code O99.89 as principal diagnosis	57	3.5	6,439

As shown in the table above, we found a total of 91 cases in MS–DRG 769 with an average length of stay of 4.3 days and average costs of $11,015. Of these 91 cases, 7 cases reported ICD–10–CM diagnosis code O99.89 as a principal diagnosis with an average length of stay of 5.6 days and average costs of $19,059, and 61 cases reported ICD–10–CM diagnosis code O99.89 as a secondary diagnosis with an average length of stay of 12.1 days and average costs of $41,717. For MS–DRG 776, we found a total of 560 cases with an average length of stay of 3.1 days and average costs of $5,332. Of these 560 cases, 57 cases reported ICD–10–CM diagnosis code O99.89 as a principal diagnosis with an average length of stay of 3.5 days and average costs of $6,439. There were no cases reporting ICD–10–CM diagnosis code O99.89 as a secondary diagnosis in MS–DRG 776.

For MS–DRG 769, the data show that the 68 cases reporting ICD–10–CM diagnosis code O99.89 as a principal or secondary diagnosis have a longer average length of stay and higher average costs compared to all the cases in MS–DRG 769. For MS–DRG 776, the data show that the 57 cases reporting a principal diagnosis of ICD–10–CM diagnosis code O99.89 have a similar average length of stay compared to all the cases in MS–DRG 776 (3.5 days versus 3.1 days) and average costs that are consistent with the average costs of all cases in MS–DRG 776 ($6,439 versus $5,332).

We note that the description for ICD–10–CM diagnosis code O99.89 ''Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium'', describes conditions that may occur during the antepartum period (pregnancy), during childbirth, or during the postpartum period (puerperium). In addition, in the ICD–10–CM Tabular List of Diseases, there is an inclusion term at subcategory O99.8- instructing users that the reporting of any diagnosis codes in that subcategory is intended for conditions that are reported in certain ranges of the classification. Specifically, the inclusion term states ''Conditions in D00–D48, H00–H95, M00–N99, and Q00–Q99.'' There is also an instructional note to ''Use additional code to identify condition.'' As a result, ICD–10–CM diagnosis code O99.89 may be reported to identify conditions that occur during the antepartum period (pregnancy), during childbirth, or during the postpartum period (puerperium). However, it is not restricted to the reporting of obstetric specific conditions only. In the example provided by the requestor, ICD–10–CM diagnosis code O99.89 was reported as the principal diagnosis with ICD–10–CM diagnosis code N13.2 (Hydronephrosis with renal and ureteral calculous obstruction) as a secondary diagnosis. ICD–10–CM diagnosis code N13.2 is within the code range referenced earlier in this section (M00–N99) and qualifies as an appropriate condition for reporting according to the instruction.

As noted earlier, ICD–10–CM diagnosis code O99.89 is intended to report conditions that occur during the antepartum period (pregnancy), during childbirth, or during the postpartum period (puerperium) and is not restricted to the reporting of obstetric specific conditions only. However, because the diagnosis code description includes three distinct obstetric related stages, it is not clear what stage the patient is in by this single code. For example, upon review of subcategory O99.8-, we recognized that the other ICD–10–CM diagnosis code sub-subcategories are expanded to include unique codes that identify the condition as occurring or complicating pregnancy, childbirth or the puerperium. Specifically, sub-subcategory O99.81- (Abnormal glucose complicating pregnancy, childbirth, and the puerperium) is expanded to include the following ICD–10–CM diagnosis codes.

ICD–10–CM code	Code description
O99.810	Abnormal glucose complicating pregnancy.
O99.814	Abnormal glucose complicating childbirth.
O99.815	Abnormal glucose complicating the puerperium.

The codes listed above specifically identify at what stage the abnormal glucose was a complicating condition. Because each code uniquely identifies a stage, the code can be easily classified under MDC 14 as an antepartum condition (ICD–10–CM diagnosis code O99.810), occurring during a delivery episode (ICD–10–CM diagnosis code O99.814), or as a postpartum condition (ICD–10–CM diagnosis code O99.815). The same is not true for ICD–10–CM diagnosis code O99.89 because it includes all three stages in the single code.

Therefore, we examined the number and type of secondary diagnoses reported with ICD–10–CM diagnosis code O99.89 as a principal diagnosis for MS–DRGs 769 and 776 to identify how many secondary diagnoses were related to other obstetric conditions and how many were related to non-obstetric conditions.

MS–DRG	Number of secondary diagnoses reported with O99.89 as principal	Number of secondary OB related diagnoses	Number of secondary OB related antepartum diagnoses	Number of secondary OB related postpartum diagnoses	Number of secondary OB related delivery diagnoses	Number of secondary non-OB related diagnoses
MS–DRG 769	59	13	11	1	1	46
MS–DRG 776	376	113	88	19	6	263

As shown in the table above, there was a total of 59 secondary diagnoses reported with diagnosis code O99.89 as the principal diagnosis for MS–DRG 769. Of those 59 secondary diagnoses, 13 were obstetric (OB) related diagnosis codes (11 antepartum, 1 postpartum and 1 delivery) and 46 were non-obstetric (Non-OB) related diagnosis codes. For MS–DRG 776, there was a total of 376 secondary diagnoses reported with diagnosis code O99.89 as the principal diagnosis. Of those 376 secondary diagnoses, 113 were obstetric (OB) related diagnosis codes (88 antepartum, 19 postpartum and 6 delivery) and 263 were non-obstetric (Non-OB) related diagnosis codes.

The data reflect that, for MS–DRGs 769 and 776, the number of secondary diagnoses identified as OB-related antepartum diagnoses is greater than the number of secondary diagnoses identified as OB-related postpartum diagnoses (99 antepartum diagnoses versus 20 postpartum diagnoses). The data also indicate that, of the 435 secondary diagnoses reported with ICD–10–CM diagnosis code O99.89 as the principal diagnosis, 309 (71 percent) of those secondary diagnoses were non-OB-related diagnosis codes. Because there was a greater number of secondary diagnoses identified as OB-related antepartum diagnoses compared to the OB-related postpartum diagnoses within the postpartum MS–DRGs when ICD–10–CM diagnosis code O99.89 was reported as the principal diagnosis, we performed further analysis of diagnosis code O99.89 within the antepartum MS–DRGs.

Under the Version 35 ICD–10 MS–DRGs, diagnosis code O99.89 was classified as an antepartum condition and was assigned to MS–DRG 781 (Other Antepartum Diagnoses with Medical Complications). Therefore, we also analyzed claims data for MS–DRGs 817, 818 and 819 (Other Antepartum Diagnoses with O.R. Procedure with MCC, with CC and without CC/MCC, respectively) and MS–DRGs 831, 832, and 833 (Other Antepartum Diagnoses without O.R. Procedure with MCC, with CC and without CC/MCC, respectively) for cases reporting ICD–10–CM diagnosis code O99.89 as a secondary diagnosis. We note that the analysis for the proposed FY 2020 ICD–10 MS–DRGs is based upon the September 2018 update of the FY 2018 MedPAR claims data that were grouped through the ICD–10 MS–DRG GROUPER Version 36. Our findings are shown in the table below.

ANTEPARTUM MS–DRGS WITH SECONDARY DIAGNOSIS OF OTHER SPECIFIED DISEASES AND CONDITIONS COMPLICATING PREGNANCY, CHILDBIRTH AND THE PUERPERIUM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 817—All cases	63	5.7	$14,948
MS–DRG 817—Cases reporting diagnosis code O99.89 as secondary diagnosis	8	10.8	24,359
MS–DRG 818—All cases	78	4.1	9,343
MS–DRG 818—Cases reporting diagnosis code O99.89 as secondary diagnosis	7	3.4	14,182
MS–DRG 819—All cases	25	2.2	5,893
MS–DRG 819—Cases reporting diagnosis code O99.89 as secondary diagnosis	1	1	4,990
MS–DRG 831—All cases	747	4.8	7,714
MS–DRG 831—Cases reporting diagnosis code O99.89 as secondary diagnosis	127	5.4	7,050
MS–DRG 832—All cases	1,142	3.6	5,159
MS–DRG 832—Cases reporting diagnosis code O99.89 as secondary diagnosis	145	4.2	5,656
MS–DRG 833—All cases	537	2.6	3,807
MS–DRG 833—Cases reporting diagnosis code O99.89 as secondary diagnosis	47	2.6	3,307

As shown in the table above, we found a total of 63 cases in MS–DRG 817 with an average length of stay of 5.7 days and average costs of $14,948. Of these 63 cases, there were 8 cases reporting ICD–10–CM diagnosis code O99.89 as a secondary diagnosis with an average length of stay of 10.8 days and average costs of $24,359. For MS–DRG 818, we found a total of 78 cases with an average length of stay of 4.1 days and average costs of $9,343. Of these 78 cases, there were 7 cases reporting ICD–10–CM diagnosis code O99.89 as a secondary diagnosis with an average length of stay of 3.4 days and average costs of $14,182. For MS–DRG 819, we found a total of 25 cases with an average length of stay of 2.2 days and average costs of $5,893. Of these 25 cases, there was 1 case reporting ICD–10–CM diagnosis code O99.89 as a secondary diagnosis with an average length of stay of 1 day and average costs of $4,990.

For MS–DRG 831, we found a total of 747 cases with an average length of stay of 4.8 days and average costs of $7,714. Of these 747 cases, there were 127 cases reporting ICD–10–CM diagnosis code O99.89 as a secondary diagnosis with an average length of stay of 5.4 days and average costs of $7,050. For MS–DRG 832, we found a total of 1,142 cases with an average length of stay of 3.6 days and average costs of $5,159. Of these 1,142 cases, there were 145 cases reporting ICD–10–CM diagnosis code O99.89 as a secondary diagnosis with an average length of stay of 4.2 days and average costs of $5,656. For MS–DRG 833, we found a total of 537 cases with an average length of stay of 2.6 days and average costs of $3,807. Of these 537 cases, there were 47 cases reporting ICD–10–CM diagnosis code O99.89 as a secondary diagnosis with an average length of stay of 2.6 days and average costs of $3,307.

Overall, there was a total of 335 cases reporting ICD–10–CM diagnosis code O99.89 as a secondary diagnosis within the antepartum MS–DRGs. Of those 335 cases, 16 cases involved an O.R. procedure and 319 cases did not involve an O.R. procedure. The data indicate that ICD–10–CM diagnosis code O99.89 is reported more often as a secondary diagnosis within the antepartum MS–DRGs (335 cases) than it is reported as a principal or secondary diagnosis within the postpartum MS–DRGs (125 cases).

Our clinical advisors believe that, because ICD–10–CM diagnosis code O99.89 can be reported during the antepartum period (pregnancy), during childbirth, or during the postpartum period (puerperium), there is not a clear clinical indication as to which set of MS–DRGs (antepartum, delivery, or postpartum) would be the most appropriate assignment for this diagnosis code. They recommended that we collaborate with the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention (CDC), in consideration of a proposal to possibly expand ICD–10–CM diagnosis code O99.89 to become a sub-subcategory that would result in the creation of unique codes with a sixth digit character to specify which obstetric related stage the patient is in. For example, under subcategory O99.8-, a proposed new sub-subcategory for ICD–10–CM diagnosis code O99.89- could include the following proposed new diagnosis codes:

- O99.890 (Other specified diseases and conditions complicating pregnancy);
- O99.894 (Other specified diseases and conditions complicating childbirth); and
- O99.85 (Other specified diseases and conditions complicating the puerperium).

If such a proposal to create this new sub-subcategory and new diagnosis codes were approved and finalized, it would enable improved data collection and more appropriate MS–DRG assignment, consistent with the current MS–DRG assignments of the existing obstetric related diagnosis codes. For instance, a new diagnosis code described as ''complicating pregnancy'' would be clinically aligned with the antepartum MS–DRGs, a new diagnosis code described as ''complicating childbirth'' would be clinically aligned with the delivery MS–DRGs, and a new diagnosis code described as ''complicating the puerperium'' would be clinically aligned with the postpartum MS–DRGs. (We note that all requests for new diagnosis codes require that a proposal be approved for discussion at a future ICD–10 Coordination and Maintenance Committee meeting.)

While our clinical advisors could not provide a strong clinical justification for classifying ICD–10–CM diagnosis code O99.89 as an antepartum condition versus as a postpartum condition for the reasons described above, they did consider the claims data to be informative as to how the diagnosis code is being reported for obstetric patients. In analyzing both the postpartum MS–DRGs and the antepartum MS–DRGs discussed earlier in this section, they agreed that the data clearly show that ICD–10–CM diagnosis code O99.89 is reported more frequently as a secondary diagnosis within the antepartum MS–DRGs than it is reported as a principal or secondary diagnosis within the postpartum MS–DRGs.

Based on our analysis of claims data and input from our clinical advisors, we are proposing to reclassify ICD–10–CM diagnosis code O99.89 from a postpartum condition to an antepartum condition under MDC 14. If finalized, ICD–10–CM diagnosis code O99.89 would follow the logic as described in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41212) which asks if there was a principal diagnosis of an antepartum condition reported on the claim. If yes, the logic then asks if there was an O.R. procedure reported on the claim. If yes, the logic assigns the case to MS–DRG 817, 818, or 819. If no (there was not an O.R. procedure reported on the claim), the logic assigns the case to MS–DRG 831, 832, or 833.

10. MDC 22 (Burns): Skin Graft to Perineum for Burn

We received a request to add seven ICD–10–PCS procedure codes that describe a skin graft to the perineum to MS–DRG 927 (Extensive Burns Or Full Thickness Burns with MV >96 Hours with Skin Graft) and MS–DRGs 928 and 929 (Full Thickness Burn with Skin Graft Or Inhalation Injury with CC/MCC and without CC/MCC, respectively) in MDC 22. The seven procedure codes are listed in the following table.

ICD–10–PCS code	Code description
0HR9X73	Replacement of perineum skin with autologous tissue substitute, full thickness, external approach.
0HR9X74	Replacement of perineum skin with autologous tissue substitute, partial thickness, external approach.
0HR9XJ3	Replacement of perineum skin with synthetic substitute, full thickness, external approach.
0HR9XJ4	Replacement of perineum skin with synthetic substitute, partial thickness, external approach.
0HR9XJZ	Replacement of perineum skin with synthetic substitute, external approach.
0HR9XK3	Replacement of perineum skin with non-autologous tissue substitute, full thickness, external approach.
0HR9XK4	Replacement of perineum skin with non-autologous tissue substitute, partial thickness, external approach.

These seven procedure codes are currently assigned to MS–DRGs 746 and 747 (Vagina, Cervix and Vulva Procedures with CC/MCC and without CC/MCC, respectively). In addition, when reported in conjunction with a principal diagnosis in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs), these codes group to MS–DRGs 907, 908, and 909 (Other O.R. Procedures For Injuries with MCC, with CC and without CC/MCC, respectively), and when reported in conjunction with a principal diagnosis in MDC 24 (Multiple Significant Trauma), these codes group to MS–DRGs 957, 958, and 959 (Other O.R. Procedures For Multiple Significant Trauma with MCC, with CC and without CC/MCC, respectively). In addition, these procedures are designated as non-extensive O.R. procedures and are assigned to MS–DRGs 987, 988 and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when a principal diagnosis that is unrelated to the procedure is reported on the claim.

The requestor provided an example in which it identified one case where a patient underwent debridement and split thickness skin graft (STSG) to the perineum area (only), and expressed concern that the case did not route to MS–DRGs 928 and 929 to recognize operating room resources. (We note that the requestor did not specify the diagnosis associated with this case nor the MS–DRG to which this one case was grouped.) The requestor stated that providers may document various terminologies for this anatomic site,

including *perineum, groin,* and *buttocks crease;* therefore, when a provider deems a burn to affect the perineum as opposed to the groin or buttock crease, cases should route to MS–DRGs which compensate hospitals for skin grafting operating room resources. Therefore, the requestor recommended that the cited seven ICD–10–PCS codes be added to the list of procedure codes for a skin graft within MS–DRGs 927, 928, and 929.

We reviewed this request by analyzing claims data from the September 2018 update of the FY 2018 MedPAR file for cases reporting any of the above seven procedure codes in MS–DRGs 746, 747, 907, 908, 909, 957, 958, 959, 987, 988, and 989. Our findings are shown in the following table.

CASES INVOLVING SKIN GRAFT TO THE PERINEUM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 746—All cases	1,344	5	$11,847
MS–DRG 746—Cases with skin graft to the perineum procedure	1	2	10,830
MS–DRG 907—All cases	7,843	10	28,919
MS–DRG 907—Cases with skin graft to the perineum procedure	1	8	21,909
MS–DRG 908—All cases	9,286	5.3	14,601
MS–DRG 908—Cases with skin graft to the perineum procedure	1	6	8,410
MS–DRG 988—All cases	8,391	5.7	12,294
MS–DRG 988—Cases with skin graft to the perineum procedure	2	3	6,906
MS–DRG 989—All cases	1,551	3.1	8,171
MS–DRG 989—Cases with skin graft to the perineum procedure	1	7	14,080

As shown in the table above, the overall volume of cases reporting a skin graft to the perineum procedure is low, with a total of 6 cases found. In MS–DRG 746, we found a total of 1,344 cases with an average length of stay of 5 days and average costs of $11,847. The single case reporting a skin graft to the perineum procedure in MS–DRG 746 had a length of stay of 2 days and a cost of $10,830. In MS–DRG 907, we found a total of 7,843 cases with an average length of stay of 10 days and average costs of $28,919. The single case reporting a skin graft to the perineum procedure in MS–DRG 907 had a length of stay of 8 days and a cost of $21,909. In MS–DRG 908, we found a total of 9,286 cases with an average length of stay of 5.3 days and average costs of $14,601. The single case reporting a skin graft to the perineum procedure in MS–DRG 908 had a length of stay of 6 days and a cost of $8,410. In MS–DRG 988, we found a total of 8,391 cases with an average length of stay of 5.7 days and average costs of $12,294. The 2 cases reporting a skin graft to the perineum procedure in MS–DRG 988 had an average length of stay of 3 days and average costs of $6,906. In MS–DRG 989, we found a total of 1,551 cases with an average length of stay of 3.1 days and average costs of $8,171. The single case reporting a skin graft to the perineum procedure in MS–DRG 989 had a length of stay of 7 day and a cost of $14,080. We found no cases reporting a skin graft to the perineum procedure in MS–DRG 747, 909, 957, 958, 959, or 987. Cases reporting a skin graft to the perineum procedure generally had shorter length of stays and lower average costs than those of their assigned MS–DRGs overall.

We then analyzed claims data for MS–DRGs 927, 928, and 929 (the MS–DRGs to which the requestor suggested that these cases group) for all cases reporting a procedure describing a skin graft to the perineum listed in the table above to consider how the resources involved in the cases reporting a procedure describing a skin graft to the perineum compared to those of all cases in MS–DRGs 927, 928, and 929. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 927—All cases	146	30.9	$147,903
MS–DRG 928—All cases	1,149	15.7	45,523
MS–DRG 928—Cases with skin graft to the perineum procedure	5	39	64,041
MS–DRG 929—All cases	296	7.9	21,474

As shown in the table above, for MS–DRG 927, we found a total of 146 cases with an average length of stay of 30.9 days and average costs of $147,903; no cases reporting a skin graft to the perineum procedure were found. For MS–DRG 928, we found a total of 1,149 cases with an average length of stay of 15.7 days and average costs of $45,523. We found 5 cases reporting a skin graft to the perineum procedure with an average length of stay of 39 days and average costs of $64,041. For MS–DRG 929, we found a total of 296 cases with an average length of stay of 7.9 days and average costs of $21,474; and no cases reporting a skin graft to the perineum procedure were found. We note that none of the 5 cases reporting a skin graft to the perineum in MS–DRGs 927, 928, and 929 reported a skin graft to the perineum procedure as the only operating room procedure. Therefore, it is not possible to determine how much of the operating room resources for these 5 cases were attributable to the skin graft to the perineum procedure.

Our clinical advisors reviewed the claims data described above and noted that none of the cases reporting the seven identified procedure codes that grouped to MS–DRGs 746, 907, 908, 988, and 989 (listed in the table above) had a principal or secondary diagnosis of a burn, which suggests that these skin grafts were not performed to treat a burn. Therefore, our clinical advisors believe that it would not be appropriate for these cases that report a skin graft to the perineum procedure to group to MS–DRGs 927, 928, and 929, which describe burns. Our clinical advisors state that the seven ICD–10–PCS procedure codes that describe a skin graft to the perineum are more clinically aligned with the other procedures in MS–DRGs 746 and 747, to which they are currently assigned. Therefore, we are

not proposing to add the seven identified procedure codes to MS–DRGs 927, 928, and 929.

11. MDC 23 (Factors Influencing Health Status and Other Contacts With Health Services): Proposed Assignment of Diagnosis Code R93.89

We received a request to consider reassignment of ICD–10–CM diagnosis code R93.89 (Abnormal finding on diagnostic imaging of other specified body structures) from MDC 5 (Diseases and Disorders of the Circulatory System) in MS–DRGs 302 and 303 (Atherosclerosis with and without MCC and Atherosclerosis without MCC, respectively) to MDC 23 (Factors Influencing Health Status and Other Contact with Health Services), consistent with other diagnosis codes that include abnormal findings. However, the requestor did not suggest a specific MS–DRG assignment within MDC 23.

We examined claims data from the September 2018 update of the FY 2018 MedPAR file for MS–DRGs 302 and 303 and identified cases reporting diagnosis code R93.89. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 302—All cases	3,750	3.8	$7,956
MS–DRG 302—Cases reporting diagnosis code R93.89	3	7.7	10,818
MS–DRG 303—All cases	12,986	2.3	4,920
MS–DRG 303—Cases reporting diagnosis code R93.89	10	2	3,416

As shown in the table, for MS–DRG 302, there was a total of 3,750 cases with an average length of stay of 3.8 days and average costs of $7,956. Of these 3,750 cases, there were 3 cases reporting abnormal finding on diagnostic imaging of other specified body structures, with an average length of stay 7.7 days and average costs of $10,818. For MS–DRG 303, there was a total of 12,986 cases with an average length of stay of 2.3 days and average costs of $4,920. Of these 12,986 cases, there were 10 cases reporting abnormal finding on diagnostic imaging of other specified body structures, with an average length of stay 2 days and average costs of $3,416.

Our clinical advisors reviewed this request and determined that the assignment of diagnosis code R93.89 to MDC 5 in MS–DRGs 302 and 303 was a result of replication from ICD–9–CM diagnosis code 793.2 (Nonspecific (abnormal) findings on radiological and other examination of other intrathoracic organs), which was assigned to those MS–DRGs. Therefore, they support reassignment of diagnosis code R93.89 to MDC 23. Our clinical advisors agree this reassignment is clinically appropriate as it is consistent with other diagnosis codes in MDC 23 that include abnormal findings from other nonspecified sites. Specifically, our clinical advisors suggest reassignment of diagnosis code R89.93 to MS–DRGs 947 and 948 (Signs and Symptoms with and without MCC, respectively). Therefore, we are proposing to reassign ICD–10–CM diagnosis code R93.89 from MDC 5 in MS–DRGs 302 and 303 to MDC 23 in MS–DRGs 947 and 948.

12. Review of Procedure Codes in MS–DRGs 981 Through 983 and 987 Through 989

a. Adding Procedure Codes and Diagnosis Codes Currently Grouping to MS–DRGs 981 Through 983 or MS–DRGs 987 Through 989 into MDCs

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned. Based on the results of our review of the claims data from the September 2018 update of the FY 2018 MedPAR file, we are proposing to move the cases reporting the procedures and/or principal diagnosis codes described below from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis or procedure is assigned.

(1) Gastrointestinal Stromal Tumors With Excision of Stomach and Small Intestine

Gastrointestinal stromal tumors (GIST) are tumors of connective tissue, and are currently assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue). The ICD–10–CM diagnosis codes describing GIST are listed in the table below.

ICD–10–CM diagnosis code	Code description
C49.A0	Gastrointestinal stromal tumor, unspecified site.
C49.A1	Gastrointestinal stromal tumor of esophagus.
C49.A2	Gastrointestinal stromal tumor of stomach.
C49.A3	Gastrointestinal stromal tumor of small intestine.
C49.A4	Gastrointestinal stromal tumor of large intestine.
C49.A5	Gastrointestinal stromal tumor of rectum.
C49.A9	Gastrointestinal stromal tumor of other sites.

During our review of cases that group to MS–DRGs 981 through 983, we noted that when procedures describing open excision of the stomach or small intestine (ICD–10–PCS procedure codes 0DB60ZZ (Excision of stomach, open approach) and 0DB80ZZ (Excision of small intestine, open approach)) were reported with a principal diagnosis of GIST, the cases group to MS–DRGs 981 through 983. These two excision codes are assigned to several MDCs, as listed in the table below. Whenever there is a surgical procedure reported on the claim, which is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

DRG Assignments for ICD–10–PCS Procedure Codes 0DB60ZZ and 0DB80ZZ

MDC	DRG	DRG Description
5	264	Other Circulatory O.R. Procedures.
6	326–328	Stomach, Esophageal and Duodenal Procedures.
10	619–621	Procedures for Obesity.
17	820–822	Lymphoma and Leukemia with Major Procedure.
17	826–828	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major Procedure.
21	907–909	Other O.R. Procedures for Injuries.
24	957–959	Other Procedures for Multiple Significant Trauma.

We first examined cases that reported a principal diagnosis of GIST and ICD–10–PCS procedure code 0DB60ZZ or 0DB80ZZ that currently group to MS–DRGs 981 through 983, as well as all cases in MS–DRGs 981 through 983. Our findings are shown in the table below.

MS–DRGs 981–983: All Cases and Cases With Principal Diagnosis of GIST and Procedure Code 0DB60ZZ or 0DB80ZZ

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—All cases	29,192	11.3	$29,862
MS–DRG 981—Cases with procedure code 0DB60ZZ	46	12.4	35,723
MS–DRG 981—Cases with procedure code 0DB80ZZ	12	10.8	28,059
MS–DRG 982—All cases	16,834	6.3	16,939
MS–DRG 982—Cases with procedure code 0DB60ZZ	104	6.8	17,442
MS–DRG 982—Cases with procedure code 0DB80ZZ	41	8	18,961
MS–DRG 983—All cases	3,166	3.3	11,872
MS–DRG 983—Cases with procedure code 0DB60ZZ	97	4.5	11,901
MS–DRG 983—Cases with procedure code 0DB80ZZ	19	4.5	9,971

Of the MDCs to which these gastrointestinal excision procedures are currently assigned, our clinical advisors indicated that cases with a principal diagnosis of GIST that also report an open gastrointestinal excision procedure code would logically be assigned to MDC 6 (Diseases and Disorders of the Digestive System). Within MDC 6, ICD–10–PCS procedures codes 0DB60ZZ and 0DB80ZZ are currently assigned to MS–DRGs 326, 327, and 328 (Stomach, Esophageal and Duodenal Procedures with MCC, CC, and without CC/MCC, respectively). To understand how the resources associated with the subset of cases reporting a principal diagnosis of GIST and procedure code 0DB60ZZ or 0DB80ZZ compare to those of cases in MS–DRGs 326, 327, and 328 as a whole, we examined the average costs and average length of stay for all cases in MS–DRGs 326, 327, and 328. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 326—All cases	9,898	13	$36,129
MS–DRG 327—All cases	9,602	6.6	18,736
MS–DRG 328—All cases	7,634	2.9	11,555

Our clinical advisors reviewed these data and noted that the average length of stay and average costs of this subset of cases were similar to those of cases in MS–DRGs 326, 327, and 328 in MDC 6. To consider whether it was appropriate to move the GIST diagnosis codes from MDC 8, we examined the other procedure codes reported for cases that report a principal diagnosis of GIST and noted that almost all of the O.R. procedures most frequently reported were assigned to MDC 6 rather than MDC 8. Our clinical advisors believe that, given the similarity in resource use between this subset of cases and cases in MS–DRGs 326, 327, and 328, and that the GIST diagnosis codes are gastrointestinal in nature, they would be more appropriately assigned to MS–DRGs 326, 327, and 328 in MDC 6 than their current assignment in MDC 8. Therefore, we are proposing to move the GIST diagnosis codes listed above from MDC 8 to MDC 6 within MS–DRGs 326, 327, and 328. Under our proposal, cases reporting a principal diagnosis of GIST would group to MS–DRGs 326, 327, and 328.

(2) Peritoneal Dialysis Catheter Complications

During our review of the cases currently grouping to MS–DRGs 981–

983, we noted that cases reporting a principal diagnosis of complications of peritoneal dialysis catheters with procedure codes describing removal, revision, and/or insertion of new peritoneal dialysis catheters group to MS–DRGs 981 through 983. The ICD–10–CM diagnosis codes that describe complications of peritoneal dialysis catheters, listed in the table below, are assigned to MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs). These principal diagnoses are frequently reported with the procedure codes describing removal, revision, and/or insertion of new peritoneal dialysis catheters.

ICD–10–CM code	Code description
T85.611A	Breakdown (mechanical) of intraperitoneal dialysis catheter, initial encounter.
T85.621A	Displacement of intraperitoneal dialysis catheter, initial encounter.
T85.631A	Leakage of intraperitoneal dialysis catheter, initial encounter.
T85.691A	Other mechanical complication of intraperitoneal dialysis catheter, initial encounter.
T85.71XA	Infection and inflammatory reaction due to peritoneal dialysis catheter, initial encounter.
T85.898A	Other specified complication of other internal prosthetic devices, implants and graft, initial encounter.

The procedure codes in the table below describe removal, revision, and/or insertion of new peritoneal dialysis catheters or revision of synthetic substitutes and are currently assigned to MDC 6 (Diseases and Disorders of the Digestive System) in MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

ICD–10–PCS procedure code	Code description
0WHG03Z	Insertion of infusion device into peritoneal cavity, open approach.
0WHG43Z	Insertion of infusion device into peritoneal cavity, percutaneous endoscopic approach.
0WPG03Z	Removal of infusion device from peritoneal cavity, open approach.
0WPG43Z	Removal of infusion device from peritoneal cavity, percutaneous endoscopic approach.
0WWG03Z	Revision of infusion device in peritoneal cavity, open approach.
0WWG0JZ	Revision of synthetic substitute in peritoneal cavity, open approach.
0WWG43Z	Revision of infusion device in peritoneal cavity, percutaneous endoscopic approach.
0WWG4JZ	Revision of synthetic substitute in peritoneal cavity, percutaneous endoscopic approach.

We examined the claims data from the September 2018 update of the FY 2018 MedPAR file for the average costs and length of stay for cases that report a principal diagnosis of complications of peritoneal dialysis catheters with a procedure describing removal, revision, and/or insertion of new peritoneal dialysis catheters or revision of synthetic substitutes. Our findings are shown in the table below. We note that we did not find any such cases in MS–DRG 983.

MS–DRG 981 Through 982: Peritoneal Dialysis Catheter Procedures With Principal Diagnosis of Complications of Peritoneal Dialysis Catheters

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—Cases reporting peritoneal dialysis catheter procedures with a principal diagnosis of complications of peritoneal dialysis catheters	1,603	8.5	$20,676
MS–DRG 982—Cases reporting peritoneal dialysis catheter procedures with a principal diagnosis of complications of peritoneal dialysis catheters	5	8.6	11,694

Our clinical advisors indicated that, within MDC 21, the procedures describing removal, revision, and/or insertion of new peritoneal dialysis catheters or revision of synthetic substitutes most suitably group to MS–DRGs 907, 908, and 909, which contain all procedures for injuries that are not specific to the hand, skin, and wound debridement. To determine how the resources for this subset of cases compared to cases in MS–DRGs 907, 908, and 909 as a whole, we examined the average costs and length of stay for cases in MS–DRGs 907, 908, and 909. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 907—All cases	9,482	9.7	$27,492
MS–DRG 908—All cases	9,305	5.3	14,597
MS–DRG 909—All cases	3,011	3	9,587

Our clinical advisors considered these data and noted that the average costs and length of stay for this subset of cases, most of which group to MS–DRG 981, are lower than the average costs and length of stay for cases of the same

severity level in MS–DRGs 907. However, our clinical advisors believe that the procedures describing removal, revision, and/or insertion of new peritoneal dialysis catheters or revision of synthetic substitutes are clearly related to the principal diagnosis codes describing complications of peritoneal dialysis catheters and, therefore, it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses. Therefore, we are proposing to add the eight procedure codes listed in the table above that describe removal, revision, and/or insertion of new peritoneal dialysis catheters or revision of synthetic substitutes to MDC 21 (Injuries, Poisonings & Toxic Effects of Drugs) in MS–DRGs 907, 908, and 909. Under this proposal, cases reporting a principal diagnosis of complications of peritoneal dialysis catheters with a procedure describing removal, revision, and/or insertion of new peritoneal dialysis catheters or revision of synthetic substitutes would group to MS–DRGs 907, 908, and 909.

(3) Bone Excision With Pressure Ulcers

During our review of the cases that group to MS–DRGs 981 through 983, we noted that when procedures describing excision of the sacrum, pelvic bones, and coccyx (ICD–10–PCS procedure codes 0QB10ZZ (Excision of sacrum, open approach), 0QB20ZZ (Excision of right pelvic bone, open approach), 0QB30ZZ (Excision of left pelvic bone, open approach), and 0QBS0ZZ (Excision of coccyx, open approach)) are reported with a principal diagnosis of pressure ulcers in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast), the cases group to MS–DRGs 981 through 983. The procedures describing excision of the sacrum, pelvic bones, and coccyx group to several MDCs, which are listed in the table below.

MS–DRG ASSIGNMENTS FOR ICD–10–PCS CODES 0QB10ZZ, 0QB20ZZ, 0QB30ZZ, AND 0QBS0ZZ

MDC	MS–DRG	MS–DRG description
3	133–134	Other Ear, Nose, Mouth and Throat O.R. Procedures with CC/MCC and without CC/MCC, respectively.
8	515–517	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively.
10	628–630	Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively.
21	907–909	Other O.R. Procedures for Injuries.
24	957–959	Other Procedures for Multiple Significant Trauma.

When cases reporting procedure codes describing excision of the sacrum, pelvic bones, and coccyx report a principal diagnosis from MDC 9, the ICD–10–CM diagnosis codes that are most frequently reported as principal diagnoses are listed below.

ICD–10–CM diagnosis code	Code description
L89.150	Pressure ulcer of sacral region, unstageable.
L89.153	Pressure ulcer of sacral region, stage 3.
L89.154	Pressure ulcer of sacral region, stage 4.
L89.214	Pressure ulcer of right hip, stage 4.
L89.224	Pressure ulcer of left hip, stage 4.
L89.314	Pressure ulcer of right buttock, stage 4.
L89.324	Pressure ulcer of left buttock, stage 4.
L89.894	Pressure ulcer of other site, stage 4.

We examined the claims data from the September 2018 update of the FY 2018 MedPAR file for the average costs and length of stay for cases that report procedures describing excision of the sacrum, pelvic bones, and coccyx in conjunction with a principal diagnosis of pressure ulcers.

MS–DRGS 981 THROUGH 983: CASES REPORTING EXCISION OF THE SACRUM, PELVIC BONES, AND COCCYX REPORTED WITH A PRINCIPAL DIAGNOSIS OF PRESSURE ULCERS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—Cases reporting excision of the sacrum, pelvic bones, and coccyx and a principal diagnosis of pressure ulcers	394	11.9	$24,398
MS–DRG 982—Cases Reporting excision of the sacrum, pelvic bones, and coccyx and a principal diagnosis of pressure ulcers	477	9.4	16,464
MS–DRG 983—Cases Reporting excision of the sacrum, pelvic bones, and coccyx and a principal diagnosis of pressure ulcers	38	4.8	8,519

Our clinical advisors indicated that, given the nature of these procedures, they could not be appropriately assigned to the specific surgical MS–DRGs within MDC 9, which are: Skin graft; skin debridement; mastectomy for malignancy; and breast biopsy, local excision, and other breast procedures. Therefore, our clinical advisors believe that these procedures would most suitably group to MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively), which contain procedures

assigned to MDC 9 that do not fit within the specific surgical MS–DRGs in MDC 9. Therefore, we examined the claims data for the average length of stay and average costs for MS–DRGs 579, 580, and 581 in MDC 9. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 579	4,091	9.2	$19,873
MS–DRG 580	10,048	5.2	11,229
MS–DRG 581	4,364	3	8,987

Our clinical advisors reviewed these data and noted that, in this subset of cases, most cases group to MS–DRGs 981 and 982 and have greater average length of stay and average costs than those cases of the same severity level in MS–DRGs 579 and 580. The smaller number of cases that group to MS–DRG 983 have lower average costs than cases in MS–DRG 581. However, our clinical advisors believe that the procedure codes describing excision of the sacrum, pelvic bones, and coccyx are clearly related to the principal diagnosis codes describing pressure ulcers, as these procedures would be performed to treat pressure ulcers in the sacrum, hip, and buttocks regions. Therefore, our clinical advisors believe that it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses. Therefore, we are proposing to add the ICD–10–PCS procedure codes describing excision of the sacrum, pelvic bones, and coccyx to MDC 9 in MS–DRGs 579, 580, and 581. Under this proposal, cases reporting a principal diagnosis in MDC 9 (such as pressure ulcers) with a procedure describing excision of the sacrum, pelvic bones, and coccyx would group to MS–DRGs 579, 580, and 581.

(4) Lower Extremity Muscle and Tendon Excision

During the review of the cases that group to MS–DRGs 981 through 983, we noted that when several ICD–10–PCS procedure codes describing excision of lower extremity muscles and tendons are reported in conjunction with ICD–10–CM diagnosis codes in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders), the cases group to MS–DRGs 981 through 983. These ICD–10–PCS procedure codes are listed in the table below, and are assigned to several MS–DRGs, which are also listed below.

ICD–10–PCS procedure code	Code description
0KBN0ZZ	Excision of right hip muscle, open approach.
0KBP0ZZ	Excision of left hip muscle, open approach.
0KBS0ZZ	Excision of right lower leg muscle, open approach.
0KBT0ZZ	Excision of left lower leg muscle, open approach.
0KBV0ZZ	Excision of right foot muscle, open approach.
0KBW0ZZ	Excision of left foot muscle, open approach.
0LBV0ZZ	Excision of right foot tendon, open approach.
0LBW0ZZ	Excision of left foot tendon, open approach.

MDC	MS–DRG	MS–DRG description
01	040–042	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or Peripheral Neurostimulator, and without CC/MCC, respectively.
08	500–502	Soft Tissue Procedures with MCC, with CC, and without CC/MCC, respectively.
09	579–581	Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively.
21	907–909	Other O.R. Procedures for Injuries.
24	957–959	Other Procedures for Multiple Significant Trauma.

The ICD–10–CM diagnosis codes in MDC 10 that are most frequently reported as the principal diagnosis with a procedure describing excision of lower extremity muscles and tendons are listed in the table below. The combination indicates debridement procedures for more complex diabetic ulcers.

ICD–10–CM procedure code	Code description
E11.621	Type 2 diabetes mellitus with foot ulcer.
E11.69	Type 2 diabetes mellitus with other specified complication.
E11.628	Type 2 diabetes mellitus with other skin complications.
E11.622	Type 2 diabetes mellitus with other skin ulcer.
E10.621	Type 1 diabetes mellitus with foot ulcer.

To understand the resource use for the subset of cases reporting procedure codes describing excision of lower extremity muscles and tendons that are currently grouping to MS–DRGs 981 through 983, we examined claims data

for the average length of stay and average costs for these cases. Our findings are shown in the table below.

MS–DRGs 981–983: Cases Reporting Procedures Describing Excision of Lower Extremity Muscles and Tendons With a Principal Diagnosis in MDC 10

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—Cases reporting excision of lower extremity muscles and tendons and a principal diagnosis in MDC 10	125	9.1	$19,031
MS–DRG 982—Cases reporting excision of lower extremity muscles and tendons and a principal diagnosis in MDC 10	561	6.2	12,000
MS–DRG 983—Cases reporting excision of lower extremity muscles and tendons and a principal diagnosis in MDC 10	16	4.8	9,003

Our clinical advisors examined cases reporting procedures describing excision of lower extremity muscles and tendons with a principal diagnosis in the MS–DRGs within MDC 10 and determined that these cases would most suitably group to MS–DRGs 622, 623, and 624 (Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders with MCC, with CC, and without CC/MCC, respectively). Therefore, we examined the average length of stay and average costs for cases assigned to MS–DRGs 622, 623, and 624. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 622	1,540	11.7	$25,114
MS–DRG 623	4,849	6.6	13,490
MS–DRG 624	232	3.7	7,442

Our clinical advisors reviewed these data and noted that most of the cases reporting procedures describing excision of lower extremity muscles and tendons group to MS–DRGs 981 and 982. For these cases, the average length of stay and average costs are lower than those of cases that currently group to MS–DRGs 622 and 623. However, our clinical advisors believe that these procedures are clearly related to the principal diagnoses in MDC 10, as they would be performed to treat skin-related complications of diabetes and, therefore, it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses. Therefore, we are proposing to add the procedure codes listed previously describing excision of lower extremity muscles and tendons to MDC 10. Under our proposal, cases reporting these procedure codes with a principal diagnosis in MDC 10 would group to MS–DRGs 622, 623, and 624.

(5) Kidney Transplantation Procedures

During our review of the cases that group to MS–DRGs 981 through 983, we noted that when procedures describing transplantation of kidneys (ICD–10–PCS procedure codes 0TY00Z0 (Transplantation of right kidney, allogeneic, open approach) and 0TY10Z0 (Transplantation of left kidney, allogeneic, open approach)) are reported in conjunction with ICD–10–CM diagnosis codes in MDC 5 (Diseases and Disorders of the Circulatory System), the cases group to MS–DRGs 981 through 983. The ICD–10–CM diagnosis codes in MDC 5 that are reported with the kidney transplantation codes are I13.0 (Hypertensive heart and chronic kidney disease with heart failure and with stage 1 through stage 4 chronic kidney disease) and I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease), which group to MDC 5. Procedure codes describing transplantation of kidneys are assigned to MS–DRG 652 (Kidney Transplant) in MDC 11. We examined claims data to identify the average length of stay and average costs for cases reporting procedure codes describing transplantation of kidneys with a principal diagnosis in MDC 5, which are currently grouping to MS–DRGs 981 through 983. Our findings are shown in the table below. We did not find any such cases in MS–DRG 983.

MS–DRGs 981 Through 983: Cases Reporting Procedures Describing Transplantation of Kidney With a Principal Diagnosis in MDC 5

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—Cases reporting transplantation of kidney and a principal diagnosis in MDC 5	285	6.8	$25,340
MS–DRG 982—Cases reporting transplantation of kidney and a principal diagnosis in MDC 5	2	3.5	21,678

Our clinical advisors examined the MS–DRGs within MDC 5 and indicated that, given the nature of the procedures compared to the specific surgical procedures contained in the other surgical MS–DRGs in MDC 5, they could not be appropriately assigned to any of the specific surgical MS–DRGs. Therefore, they determined that these cases would most suitably group to MS–DRG 264 (Other Circulatory System O.R. Procedures), which contains a broader range of procedures related to MDC 5 diagnoses. We examined claims data to determine the average length of stay and

average costs for cases assigned to MS–DRG 264. We found a total of 10,073 cases, with an average length of stay of 9.3 days and average costs of $22,643.

Our clinical advisors reviewed these data and noted that the average costs for cases reporting transplantation of kidney with a diagnosis from MDC 5 are similar to the average costs of cases in MS–DRG 264 ($22,643 in MS–DRG 264 compared to $25,340 in MS–DRG 981), while the average length of stay is shorter than that of cases in MS–DRG 264 (9.3 days in MS–DRG 264 compared to 6.8 days in MS–DRG 981). Our clinical advisors noted that ICD–10–CM diagnosis codes describing hypertensive heart and chronic kidney disease without heart failure (I13.10 (Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease) and I13.11 (Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease group) group to MS–DRG 652 (Kidney Transplant) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). Our clinical advisors also noted that the counterpart codes describing hypertensive heart and chronic kidney disease with heart failure are as related to the kidney transplantation codes as the codes without heart failure, but because the codes with heart failure group to MDC 5, cases reporting a kidney transplant procedure with a diagnosis code of hypertensive heart and chronic kidney disease with heart failure currently group to MS–DRGs 981 through 983. Therefore, we are proposing to add ICD–10–PCS procedure codes 0TY00Z0 and 0TY10Z0 to MS–DRG 264 in MDC 5. Under this proposal, cases reporting a principal diagnosis in MDC 5 with a procedure describing kidney transplantation would group to MS–DRG 264 in MDC 5. We note that because MDC 5 covers the circulatory system, and kidney transplants generally group to MDC 11, we are seeking public comments on whether the procedure codes should instead continue to group to MS–DRGs 981 through 983.

(6) Insertion of Feeding Device

During our review of the cases that group to MS–DRGs 981 through 983, we noted that when ICD–10–PCS procedure code 0DH60UZ (Insertion of feeding device into stomach, open approach) is reported with ICD–10–CM diagnosis codes assigned to MDC 1 (Diseases and Disorders of the Nervous System) or MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders), the cases group to MS–DRGs 981 through 983. ICD–10–PCS procedure code 0DH60UZ is currently assigned to MDC 6 (Diseases and Disorders of the Digestive System) in MS–DRGs 326, 327, and 328 (Stomach, Esophageal and Duodenal Procedures) and MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) in MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries). We also noticed that: (1) When ICD–10–PCS procedure code 0DH60UZ is reported with a principal diagnosis in MDC 1, the ICD–10–CM diagnosis codes reported with this procedure code describe cerebral infarctions of various etiology and anatomic locations and resulting complications; and (2) when ICD–10–PCS procedure code 0DH60UZ is reported with a principal diagnosis in MDC 10, the ICD–10–CM diagnosis codes reported with this procedure code pertain to dehydration, failure to thrive, and various forms of malnutrition.

We examined claims data to identify the average length of stay and average costs for cases in MS–DRGs 981 through 983 reporting ICD–10–PCS procedure code 0DH60UZ in conjunction with a principal diagnosis from MDC 1 or MDC 10. Our findings are shown in the table below.

MS–DRGs 981 Through 983: Cases Reporting Procedure Code 0DH60UZ With a Principal Diagnosis in MDC 1 or MDC 10

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—Cases reporting procedure code 0DH60UZ and a principal diagnosis in MDC 1	115	19.3	$40,598
MS–DRG 982—Cases reporting procedure code 0DH60UZ and a principal diagnosis in MDC 1	43	13.2	25,042
MS–DRG 983—Cases reporting procedure code 0DH60UZ and a principal diagnosis in MDC 1	4	14.3	26,954
MS–DRG 981—Cases reporting procedure code 0DH60UZ and a principal diagnosis in MDC 10	47	13.4	24,690
MS–DRG 982—Cases reporting procedure code 0DH60UZ and a principal diagnosis in MDC 10	20	7.2	12,792
MS–DRG 983—Cases reporting procedure code 0DH60UZ and a principal diagnosis in MDC 10	5	5.0	8,608

Our clinical advisors determined that the feeding tube procedure was related to specific diagnoses within MDC 1 and MDC 10 and, therefore, could be assigned to both MDCs. Therefore, they reviewed the MS–DRGs within MDC 1 and MDC 10. They determined that the most suitable MS–DRG assignment within MDC 1 would be MS–DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or Peripheral Neurostimulator, and without CC/MCC, respectively), which contain procedures assigned to MDC 1 that describe insertion of devices into anatomical areas that are not part of the nervous system. Our clinical advisors determined that the most suitable MS–DRG assignment within MDC 10 would be MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively), which contain the most clinically similar procedures assigned to MDC 10, such as those describing insertion of infusion pump into subcutaneous tissue and fascia. Therefore, we examined claims data to identify the average length of stay and average costs for cases assigned to MDC 1 in MS–DRGs 040, 041, and 042 and MDC 10 in MS–DRGs 628, 629, and 630. Our findings are shown in the tables below.

MS–DRGs in MDC 1	Number of cases	Average length of stay	Average costs
MS–DRG 040	4,211	10.2	$27,096
MS–DRG 041	6,153	5.1	16,917
MS–DRG 042	2,249	3.0	13,365

MS–DRGs in MDC 10	Number of cases	Average length of stay	Average costs
MS–DRG 628	3,004	9.9	$25,472
MS–DRG 629	5,435	7.2	16,391
MS–DRG 630	237	3.2	10,659

Our clinical advisors reviewed these data and noted that the average length of stay and average costs for the subset of cases reporting ICD–10–PCS procedure code 0DH60UZ with a principal diagnosis assigned to MDC 1 are higher than those cases in MS–DRGs 040, 041, and 042. For example, the cases reporting ICD–10–PCS procedure code 0DH60UZ and a principal diagnosis in MDC 1 that currently group to MS–DRG 981 have an average length of stay of 19.3 days and average costs of $40,598, while the cases in MS–DRG 040 have an average length of stay of 10.2 days and average costs of $27,096. Our clinical advisors noted that the average length of stay and average costs for the subset of cases reporting ICD–10–PCS procedure code 0DH60UZ with a principal diagnosis assigned to MDC 10 are more closely aligned with those cases in MS–DRGs 628, 629, and 630. In both cases, our clinical advisors believe that the insertion of feeding device is clearly related to the principal diagnoses in MDC 1 and MDC 10 and, therefore, it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses. Therefore, we are proposing to add ICD–10–PCS procedure code 0DH60UZ to MDC 1 and MDC 10. Under this proposal, cases reporting procedure code 0DH60UZ with a principal diagnosis in MDC 1 would group to MS–DRGs 040, 041, and 042, while cases reporting ICD–10–PCS procedure code 0DH60UZ with a principal diagnosis in MDC 10 would group to MS–DRGs 628, 629, and 630.

(7) Basilic Vein Reposition in Chronic Kidney Disease

During our review of the cases that group to MS–DRGs 981 through 983, we noted that when procedures codes describing reposition of basilic vein (ICD–10–PCS procedure codes 05SB0ZZ (Reposition right basilic vein, open approach), 05SB3ZZ (Reposition right basilic vein, percutaneous approach), 05SC0ZZ (Reposition left basilic vein, open approach), and 05SC3ZZ (Reposition left basilic vein, percutaneous approach)) are reported with a principal diagnosis in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) (typically describing chronic kidney disease), the cases group to MS–DRGs 981 through 983. This code combination suggests a revision of an arterio-venous fistula in a patient on chronic hemodialysis. We examined claims data to identify the average length of stay and average costs for cases reporting procedures describing reposition of basilic vein with a principal diagnosis in MDC 11, which are currently grouping to MS–DRGs 981 through 983. Our findings are shown in the table below.

MS–DRGs 981–983: Cases Reporting Procedures Describing Reposition of Basilic Vein With Principal Diagnosis in MDC 11

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—Cases reporting procedures describing reposition of basilic vein and a principal diagnosis in MDC 11	48	4.6	$12,232
MS–DRG 982—Cases reporting procedures describing reposition of basilic vein and a principal diagnosis in MDC 11	10	6.9	18,481
MS–DRG 983—Cases reporting procedures describing reposition of basilic vein and a principal diagnosis in MDC 11	1	3.0	3,552

Our clinical advisors examined claims data for cases in the MS–DRGs within MDC 11 and determined that cases reporting procedures describing reposition of basilic vein with a principal diagnosis in MDC 11 would most suitably group to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively), to which MDC 11 procedures describing reposition of veins (other than renal veins) are assigned. Therefore, we examined claims data to identify the average length of stay and average costs for cases assigned to MS–DRGs 673, 674, and 675. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 673	10,542	10.8	$25,842
MS–DRG 674	6,167	7.4	17,685
MS–DRG 675	437	3.9	11,858

Our clinical advisors reviewed these data and noted that the average length of stay and average costs for cases reporting procedures describing reposition of basilic vein with a principal diagnosis in MDC 11 with an MCC are significantly lower than for those cases in MS–DRG 673. The average length of stay and average costs are similar for those cases with a CC, while the single case without a CC or MCC had significantly lower costs than the average costs of cases in MS–DRG 675. However, our clinical advisors believe that when the procedures describing reposition of basilic vein are reported with a principal diagnosis describing chronic kidney disease, the procedure is likely related to arteriovenous fistulas for dialysis associated with the chronic kidney disease. Therefore, our clinical advisors believe that it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses. Therefore, we are proposing to add ICD–10–PCS procedures codes 05SB0ZZ, 05SB3ZZ, 05SC0ZZ, and 05SC3ZZ to MDC 11. Under our proposal, cases reporting procedure codes describing reposition of basilic vein with a principal diagnosis in MDC 11 would group to MS–DRGs 673, 674, and 675.

(8) Colon Resection With Fistula

During our review of the cases that group to MS–DRGs 981 through 983, we noted that when ICD–10–PCS procedure code 0DTN0ZZ (Resection of sigmoid colon, open approach) is reported with a principal diagnosis in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract), the cases group to MS–DRGs 981 through 983. The principal diagnosis most frequently reported with ICD–10–PCS procedure code 0DTN0ZZ in MDC 11 is ICD–10–CM code N321 (Vesicointestinal fistula). ICD–10–PCS procedure code 0DTN0ZZ currently groups to several MDCs, which are listed in the table below.

MS–DRG ASSIGNMENTS FOR ICD–10–PCS PROCEDURE CODE 0DTN0ZZ

MDC	MS–DRG	MS–DRG description
6	329–331	Major Small and Large Bowel Procedures.
17	820–822	Lymphoma and Leukemia with Major Procedure.
17	826–828	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major Procedure.
21	907–909	Other O.R. Procedures for Injuries.
24	957–959	Other Procedures for Multiple Significant Trauma.

We examined claims data to identify the average length of stay and average costs for cases reporting procedure code 0DTN0ZZ with a principal diagnosis in MDC 11, which are currently grouping to MS–DRGs 981 through 983. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—Cases reporting procedure code 0DTN0ZZ and a principal diagnosis in MDC 11	27	15.81	$44,743
MS–DRG 982—Cases reporting procedure code 0DTN0ZZ and a principal diagnosis in MDC 11	33	8.48	20,105
MS–DRG 983—Cases reporting procedure code 0DTN0ZZ and a principal diagnosis in MDC 11	5	3.60	12,351

Our clinical advisors examined the MS–DRGs within MDC 11 and determined that the cases reporting procedure code 0DTN0ZZ with a principal diagnosis in MDC 11 would most suitably group to MS–DRGs 673, 674, and 675, which contain procedures performed on structures other than kidney and urinary tract anatomy. We note that the claims data describing the average length of stay and average costs for cases in these MS–DRGs are included in a table earlier in this section. Because vesicointestinal fistulas involve both the bladder and the bowel, some procedures in both MDC 6 (Diseases and Disorders of the Digestive System) and MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) would be expected to be related to a principal diagnosis of vesicointestinal fistula (ICD–10–CM code N321). Our clinical advisors observed that procedure code 0DTN0ZZ is the second most common procedure reported in conjunction with a principal diagnosis of code N321, after ICD–10–PCS procedure code 0TQB0ZZ (Repair bladder, open approach), which is assigned to both MDC 6 and MDC 11. Our clinical advisors reviewed the data and noted that the average length of stay and average costs for this subset of cases are generally higher for this subset of cases than for cases in MS–DRGs 673, 674, and 675. However, our clinical advisors believe that when ICD–10–PCS procedure code 0DTN0ZZ is reported with a principal diagnosis in MDC 11 (typically vesicointestinal fistula), the procedure is related to the principal diagnosis. Therefore, we are proposing to add ICD–10–PCS procedure code 0DTN0ZZ to MDC 11. Under our proposal, cases reporting procedure code 0DTN0ZZ with a principal diagnosis of vesicointestinal fistula (diagnosis code N321) in MDC 11 would group to MS–DRGs 673, 674, and 675.

b. Reassignment of Procedures Among MS–DRGs 981 Through 983 and 987 Through 989

We also review the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those two groups of MS–DRGs to the other group of MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

Based on the results of our review of claims data in the September 2018 update of the FY 2018 MedPAR file, we are not proposing to change the current structure of MS–DRGs 981 through 983 and MS–DRGs 987 through 989.

c. Proposed Additions for Diagnosis and Procedure Codes to MDCs

Below we summarize the requests we received to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS–DRGs to which the procedure codes are assigned.

(1) Stage 3 Pressure Ulcers of the Hip

We received a request to reassign cases for a stage 3 pressure ulcer of the left hip when reported with procedures involving excision of pelvic bone or transfer of hip muscle from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRG 579 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC) in MDC 9. ICD–10–CM diagnosis code L89.223 (Pressure ulcer left hip, stage 3) is used to report this condition and is currently assigned to MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast). We refer readers to section II.12.a. of the preamble of this proposed rule, where we address ICD–10–PCS procedure code 0QB30ZZ (Excision of left pelvic bone, open approach), which was reviewed as part of our ongoing analysis of the unrelated MS–DRGs and which we are proposing to add to MS–DRGs 579, 580, and 581 in MDC 5. (While the requestor only referred to base MS–DRG 579, we believe it is appropriate to assign the cases to MS–DRGs 579, 580, and 581 by severity level.) ICD–10–PCS procedure codes 0KXP0ZZ (Transfer left hip muscle, open approach) and 0KXN0ZZ (Transfer right hip muscle, open approach) may be reported to describe transfer of hip muscle procedures and are currently assigned to MDC 1 (Diseases and Disorders of the Nervous System) and MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue). We included ICD–10–PCS procedure code 0KXN0ZZ in our analysis because it describes the identical procedure on the right side.

Our analysis of this grouping issue confirmed that, when a stage 3 pressure ulcer of the left hip (ICD–10–CM diagnosis code L89.223) is reported as a principal diagnosis with ICD–10–PCS procedure code 0KXP0ZZ or 0KXN0ZZ, these cases group to MS–DRGs 981, 982, and 983. The reason for this grouping is because whenever there is a surgical procedure reported on a claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures.'' In the example provided, because ICD–10–CM diagnosis code L89.223 describing a stage 3 pressure ulcer of left hip is classified to MDC 9 and because ICD–10–PCS procedure codes 0KXP0ZZ and 0KXN0ZZ are classified to MDC 1 (Diseases and Disorders of the Nervous System) in MS–DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or Peripheral Neurostimulator, and without CC/MCC, respectively) and MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 500, 501, and 502 (Soft Tissue Procedures with MCC, with CC, and without CC/MCC, respectively), the GROUPER logic assigns this case to the ''unrelated operating room procedures'' set of MS–DRGs.

For our review of this grouping issue and the request to have procedure code 0KXP0ZZ added to MDC 9, we examined claims data for cases reporting procedure code 0KXP0ZZ or 0KXN0ZZ in conjunction with a diagnosis code that typically groups to MDC 9. Our findings are shown in the table below.

MS–DRGs 981 Through 983: Cases With Hip Muscle Transfer and Principal Diagnosis in MDC 9

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—Cases with procedure code 0KXP0ZZ or 0KXN0ZZ and principal diagnosis in MDC 9	72	12.6	$25,023
MS–DRG 982—Cases with procedure code 0KXP0ZZ or 0KXN0ZZ and principal diagnosis in MDC 9	130	10.5	17,955
MS–DRG 983—Cases with procedure code 0KXP0ZZ or 0KXN0ZZ and principal diagnosis in MDC 9	16	6.5	13,196

As indicated earlier, the requestor suggested that we move ICD–10–PCS procedure code 0KXP0ZZ to MS–DRG 579. However, our clinical advisors believe that, within MDC 9, these procedure codes are more clinically aligned with the procedure codes assigned to MS–DRGs 573, 574, and 575 (Skin Graft for Skin Ulcer or Cellulitis with MCC, with CC and without CC/MCC, respectively), which are more specific to the care of stage 3, 4 and unstageable pressure ulcers than MS–DRGs 579, 580, and 581. Therefore, we examined claims data to identify the average length of stay and average costs for cases assigned to MS–DRGs 573, 574, and 575. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 573	548	15.4	$34,549
MS–DRG 574	1,254	9.8	21,251
MS–DRG 575	238	5.4	12,006

We note that the average costs for cases in MS–DRGs 573 and 574 are higher than the average costs of the subset of cases with the same severity reporting a hip muscle transfer and a principal diagnosis in MDC 9, while the average costs of those cases in MS–DRG 575 are similar to the average costs of those cases that are currently grouping

to MS–DRG 983. However, our clinical advisors believe that the cases of hip muscle transfer represent a distinct, recognizable clinical group similar to those cases in MS–DRGs 573, 574, and 575, and that the procedures are clearly related to the principal diagnosis codes. Therefore, they believe that it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses. Therefore, we are proposing to add ICD–10–PCS procedure codes 0KXP0ZZ and 0KXN0ZZ to MDC 9. Under our proposal, cases reporting ICD–10–PCS procedure code 0KXP0ZZ or 0KXN0ZZ with a principal diagnosis in MDC 9 would group to MS–DRGs 573, 574, and 575.

(2) Gastrointestinal Stromal Tumor

We received a request to reassign cases for gastrointestinal stromal tumor of the stomach when reported with a procedure describing laparoscopic bypass of the stomach to jejunum from MS–DRGs 981, 982, and 983 to MS–DRGs 326, 327, and 328 (Stomach, Esophageal and Duodenal Procedures with MCC, with CC, and without CC/MCC, respectively) by adding ICD–10–PCS procedure code 0D164ZA (Bypass stomach to jejunum, percutaneous endoscopic approach) to MDC 6. ICD–10–CM diagnosis code C49.A2 (Gastrointestinal stromal tumor of stomach) is used to report this condition and is currently assigned to MDC 8. ICD–10–PCS procedure code 0D164ZA is used to report the stomach bypass procedure and is currently assigned to MDC 5 (Diseases and Disorders of the Circulatory System), MDC 6 (Diseases and Disorders of the Digestive System), MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas), MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders), and MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms). We refer readers to section II.12.a. of the preamble of this proposed rule where we discuss our proposal to move the listed diagnosis codes describing gastrointestinal stromal tumors, including ICD–10–CM diagnosis code C49.A2, into MDC 6. Therefore, this proposal, if finalized, would address the cases grouping to MS–DRGs 981 through 983 by instead moving the diagnosis codes to MDC 6, which would result in the diagnosis code and the procedure code referenced by the requestor grouping to the same MDC.

(3) Finger Cellulitis

We received a request to reassign cases for cellulitis of the right finger when reported with a procedure describing open excision of the right finger phalanx from MS–DRGs 981, 982, and 983 to MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively). Currently, ICD–10–CM diagnosis code L03.011 (Cellulitis of right finger) is used to report this condition and is currently assigned to MDC 09 in MS–DRGs 573, 574, and 575 (Skin Graft for Skin Ulcer or Cellulitis with MCC, CC, and without CC/MCC, respectively), 576, 577, and 578 (Skin Graft except for Skin Ulcer or Cellulitis with MCC, CC, and without CC/MCC, respectively), and 602 and 603 (Cellulitis with MCC and without MCC, respectively). ICD–10–PCS procedure code 0PBT0ZZ (Excision of right finger phalanx, open approach) is used to identify the excision procedure, and is currently assigned to MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat) in MS–DRGs 133 and 134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with CC/MCC, and without CC/MCC, respectively); MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively); MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders) in MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively); MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) in MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively); and MDC 24 (Multiple Significant Trauma) in MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively).

Our analysis of this grouping issue confirmed that when a procedure such as open excision of right finger phalanx (ICD–10–PCS procedure code 0PBT0ZZ) is reported with a principal diagnosis from MDC 9, such as cellulitis of the right finger (ICD–10–CM diagnosis code L03.011), these cases group to MS–DRGs 981, 982, and 983. During our review of this issue, we also examined claims data for similar procedures describing excision of phalanges (which are listed in the table below) and noted the same pattern. We further noted that the ICD–10–PCS procedure codes describing excision of phalanx procedures with the diagnostic qualifier ''X'', which are used to report these procedures when performed for diagnostic purposes, are already assigned to MS–DRGs 579, 580, and 581 (to which the requestor suggested these cases group). Our clinical advisors also believe that procedures describing resection of phalanges should be assigned to the same MS–DRG as the excisions, because the resection procedures would also group to MS–DRGs 981, 982, and 983 when reported with a principal diagnosis from MDC 9.

ICD–10–PCS procedure code	Code description
0PBR0ZZ	Excision of right thumb phalanx, open approach.
0PBR3ZZ	Excision of right thumb phalanx, percutaneous approach.
0PBR4ZZ	Excision of right thumb phalanx, percutaneous endoscopic approach.
0PBS0ZZ	Excision of left thumb phalanx, open approach.
0PBS3ZZ	Excision of left thumb phalanx, percutaneous approach.
0PBS4ZZ	Excision of left thumb phalanx, percutaneous endoscopic approach.
0PBT0ZZ	Excision of right finger phalanx, open approach.
0PBT3ZZ	Excision of right finger phalanx, percutaneous approach.
0PBT4ZZ	Excision of right finger phalanx, percutaneous endoscopic approach.
0PBV0ZZ	Excision of left finger phalanx, open approach.
0PBV3ZZ	Excision of left finger phalanx, percutaneous approach.
0PBV4ZZ	Excision of left finger phalanx, percutaneous endoscopic approach.
0PTR0ZZ	Resection of right thumb phalanx, open approach.
0PTS0ZZ	Resection of left thumb phalanx, open approach.
0PTT0ZZ	Resection of right finger phalanx, open approach.
0PTV0ZZ	Resection of left finger phalanx, open approach.
0RTW0ZZ	Resection of right finger phalangeal joint, open approach.

ICD–10–PCS procedure code	Code description
0RTX0ZZ	Resection of left finger phalangeal joint, open approach.

As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

We examined the claims data for the three codes describing cellulitis of the finger (ICD–10–CM diagnosis codes L03.011 (Cellulitis of the right finger), L03.012 (Cellulitis of left finger), and L03.019 (Cellulitis of unspecified finger)) to identify the average length of stay and average costs for cases reporting a principal diagnosis of cellulitis of the finger in conjunction with the excision of phalanx procedures listed in the table above. We note that there were no cases reporting a principal diagnosis of cellulitis of the finger in conjunction with the resection of phalanx procedures listed in the table above.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—Cases with principal diagnosis of cellulitis of the finger and excision of phalanx procedure	2	3.5	$7,934
MS–DRG 982—Cases with principal diagnosis of cellulitis of the finger and excision of phalanx procedure	11	4.2	7,244
MS–DRG 983—Cases with principal diagnosis of cellulitis of the finger and excision of phalanx procedure	4	4.8	8,058

We also examined the claims data to identify the average length of stay and average costs for all cases in MS–DRGs 579, 580, and 581. Our findings are shown in the table in section II.12.A.3.of the preamble of this proposed rule.

While our clinical advisors noted that the average length of stay and average costs for cases in MS–DRGs 579, 580, and 581 are generally higher than the average length of stay and average costs for the subset of cases reporting a principal diagnosis of cellulitis of the finger and a procedure describing excision of phalanx, they believe that the procedures are clearly related to the principal diagnosis codes and, therefore, it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses, particularly given that procedures describing excision of phalanx with the diagnostic qualifier ''X'' are already assigned to these MS–DRGs. In addition, our clinical advisors believe it is clinically appropriate for the procedures describing resection of phalanx to be assigned to MS–DRGs 579, 580, and 581 as well. Therefore, we are proposing to add the procedure codes describing excision and resection of phalanx listed above to MS–DRGs 579, 580, and 581. Under this proposal, cases reporting one of the excision or resection procedures listed in the table above in conjunction with a principal diagnosis from MDC 9 would group to MS–DRGs 579, 580, and 581.

(4) Multiple Trauma With Internal Fixation of Joints

We received a request to reassign cases involving multiple significant trauma with internal fixation of joints from MS–DRGs 981, 982, and 983 to MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively). The requestor provided an example of several ICD–10–CM diagnosis codes that together described multiple significant trauma in conjunction with ICD–10–PCS procedure codes beginning with the prefix ''0SH'' and ''0RH'' that describe internal fixation of joints. The requestor provided several suggestions to address this assignment, including: Adding all ICD–10–PCS procedure codes in MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) with the exception of codes that group to MS–DRG 956 (Limb Reattachment, Hip and Femur Procedures for Multiple Significant Trauma) to MS–DRGs 957, 958, and 959; adding codes within the ''0SH'' and ''0RH'' code ranges to MDC 24; and adding ICD–10–PCS procedure codes from all MDCs except those that currently group to MS–DRG 955 (Craniotomy for Multiple Significant Trauma) or MS–DRG 956 (Limb Reattachment, Hip and Femur Procedures for Multiple Significant Trauma) to MS–DRGs 957, 958, and 959.

While we understand the requestor's concern about these multiple significant trauma cases, we believe any potential reassignment of these cases requires significant analysis. Similar to our analysis of MDC 14 (initially discussed at 81 FR 56854), there are multiple logic lists in MDC 24 that would need to be reviewed. For example, to satisfy the logic for multiple significant trauma, the logic requires a diagnosis code from the significant trauma principal diagnosis list and two or more significant trauma diagnoses from different body sites. The significant trauma logic lists for the other body sites (which include head, chest, abdominal, kidney, urinary system, pelvis or spine, upper limb, and lower limb) allow the extensive list of diagnosis codes included in the logic to be reported as a principal or secondary diagnosis. The analysis of the reporting of all the codes as a principal and/or secondary diagnosis within MDC 24, combined with the analysis of all of the ICD–10–PCS procedure codes within MDC 8, is anticipated to be a multi-year effort. Therefore, we plan to consider this issue for future rulemaking as part of our ongoing analysis of the unrelated procedure MS–DRGs.

(5) Totally Implantable Vascular Access Devices

We received a request to reassign cases for insertion of totally implantable vascular access devices (TIVADs) listed in the table below when reported with principal diagnoses in MDCs other than MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) and MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) from MS–DRGs 981 through 983 to a surgical MS–DRG within the appropriate MDC based on the principal diagnosis. The requestor noted that the insertion of

TIVAD procedures are newly designated as O.R. procedures, effective October 1, 2018, and are assigned to MDCs 9 and 11. The requestor stated that TIVADs can be placed for a variety of purposes and are used to treat a wide range of malignancies at various sites and, therefore, would likely have a relationship to the principal diagnosis within any MDC. The requestor suggested that procedures describing the insertion of TIVADs group to surgical MS–DRGs within every MDC (other than MDCs 2, 20, and 22, which do not contain surgical MS–DRGs). The requestor further stated that the surgical hierarchy should assign more significant O.R. procedures within each MDC to a higher position than procedures describing the insertion of TIVADs because these procedures consume less O.R. resources than more invasive procedures.

ICD–PCS code	Code description
0JH60WZ	Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, open approach.
0JH80WZ	Insertion of totally implantable vascular access device into abdomen subcutaneous tissue and fascia, open approach.
0JHD0WZ	Insertion of totally implantable vascular access device into right upper arm subcutaneous tissue and fascia, open approach.
0JHF0WZ	Insertion of totally implantable vascular access device into left upper arm subcutaneous tissue and fascia, open approach.
0JHG0WZ	Insertion of totally implantable vascular access device into right lower arm subcutaneous tissue and fascia, open approach.
0JHH0WZ	Insertion of totally implantable vascular access device into left lower arm subcutaneous tissue and fascia, open approach.
0JHL0WZ	Insertion of totally implantable vascular access device into right upper leg subcutaneous tissue and fascia, open approach.
0JHM0WZ	Insertion of totally implantable vascular access device into left upper leg subcutaneous tissue and fascia, open approach.
0JHN0WZ	Insertion of totally implantable vascular access device into right lower leg subcutaneous tissue and fascia, open approach.
0JHP0WZ	Insertion of totally implantable vascular access device into left lower leg subcutaneous tissue and fascia, open approach.

While we agree that TIVAD procedures may be performed in connection with a variety of principal diagnoses, we note that because these procedures are newly designated as O.R. procedures effective October 1, 2018, we do not yet have sufficient data to analyze this request. We plan to consider this issue in future rulemaking as part of our ongoing analysis of the unrelated procedure MS–DRGs.

(6) Gastric Band Procedure Complications or Infections

We received a request to reassign cases for infection or complications due to gastric band procedures when reported with a procedure describing revision of or removal of extraluminal device in/from the stomach from MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively) to MS–DRGs 326, 327, and 328 (Stomach, Esophageal, and Duodenal Procedures with MCC, with CC, and without CC/MCC, respectively). ICD–10–CM diagnosis codes K95.01 (Infection due to gastric band procedure) and K95.09 (Other complications of gastric band procedure) are used to report these conditions and are currently assigned to MDC 6 (Diseases and Disorders of the Digestive System). ICD–10–PCS procedure codes 0DW64CZ (Revision of extraluminal device in stomach, percutaneous endoscopic approach) and 0DP64CZ (Removal of extraluminal device from stomach, percutaneous endoscopic approach) are used to report the revision of, or removal of, an extraluminal device in/from the stomach and are currently assigned to MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders) in MS–DRGs 619, 620, and 621 (O.R. Procedures for Obesity with MCC with CC, and without CC/MCC, respectively).

Our analysis of this grouping issue confirmed that when procedures describing the revision of or removal of an extraluminal device in/from the stomach are reported with principal diagnoses in MDC 6 (such as ICD–10–CM diagnosis codes K95.01 and K95.09), in the absence of a procedure assigned to MDC 6, these cases group to MS–DRGs 987, 988, and 989. As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

We examined the claims data to identify cases involving ICD–10–PCS procedure codes 0DW64CZ and 0DP64CZ reported with a principal diagnosis of K95.01 or K95.09 that are currently grouping to MS–DRGs 987, 988, and 989. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 987—All cases	8,674	11	$23,885
MS–DRG 987—Cases reporting procedure code 0DW64CZ or 0DP64CZ and principal diagnosis code K95.01 or K95.09	20	6.6	17,873
MS–DRG 988—All cases	8,391	5.7	12,294
MS–DRG 988—Cases reporting procedure code 0DW64CZ or 0DP64CZ and principal diagnosis code K95.01 or K95.09	105	2.2	7,253
MS–DRG 989—All cases	1,551	3.1	8,171
MS–DRG 989—Cases reporting procedure code 0DW64CZ or 0DP64CZ and principal diagnosis code K95.01 or K95.09	120	1.6	6,010

We also examined the data for cases in MS–DRGs 326, 327, and 328, and our findings are provided in a table presented in section II.12.a. of the preamble of this proposed rule. While our clinical advisors noted that the average length of stay and average costs of cases in MS–DRGs 326, 327, and 328 are significantly higher than the average length of stay and average costs for the subset of cases reporting procedure code 0DW64CZ or 0DP64CZ and a principal diagnosis code of K95.01 or K95.09, they believe that the procedures are clearly related to the principal diagnosis and, therefore, it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal

diagnoses. In addition, our clinical advisors believe that because these procedures are intended to treat a complication of a procedure related to obesity, rather than the obesity itself, they are more appropriately assigned to stomach, esophageal, and duodenal procedures (MS–DRGs 326, 327, and 328) in MDC 6 than to procedures for obesity (MS–DRGs 619, 620, and 621) in MDC 10.

Therefore, we are proposing to add ICD–10–PCS procedure codes 0DW64CZ and 0DP64CZ to MDC 6 in MS–DRGs 326, 327, and 328. Under this proposal, cases reporting procedure code 0DW64CZ or 0DP64CZ in conjunction with a principal diagnosis code of K95.01 or K95.09 would group to MS–DRGs 326, 327, and 328.

(7) Peritoneal Dialysis Catheters

We received a request to reassign cases for complications of peritoneal dialysis catheters when reported with procedure codes describing removal, revision, and/or insertion of new peritoneal dialysis catheters from MS–DRGs 981 through 983 to MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 6 by adding the diagnosis codes describing complications of peritoneal dialysis catheters to MDC 6. We refer readers to section II.12.a. of the preamble of this proposed rule in which we describe our analysis of this issue as part of our broader review of the unrelated MS–DRGs. Our clinical advisors believe it is more appropriate to add the procedure codes describing removal, revision, and/or insertion of new peritoneal dialysis catheters to MS–DRGs 907, 908, and 909 than to move the diagnosis codes describing complications of peritoneal dialysis catheters to MDC 6 because the diagnosis codes describe complications, rather than initial placement, of peritoneal dialysis catheters, and therefore, are most clinically aligned with the diagnosis codes assigned to MDC 21 (where they are currently assigned). In section II.12.a. of the preamble of this proposed rule, we are proposing to add procedures describing removal, revision, and/or insertion of peritoneal dialysis catheters to MS–DRGs 907, 908, and 909 in MDC 21.

(8) Occlusion of Left Renal Vein

We received a request to reassign cases for varicose veins in the pelvic region when reported with an embolization procedure from MS–DRGs 981, 982 and 983 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 715 and 716 (Other Male Reproductive System O.R. Procedures for Malignancy with CC/MCC and without CC/MCC, respectively) and MS–DRGs 717 and 718 (Other Male Reproductive System O.R. Procedures Except Malignancy with CC/MCC and without CC/MCC, respectively) in MDC 12 (Diseases and Disorders of the Male Reproductive System) and to MS–DRGs 749 and 750 (Other Female Reproductive System O.R. Procedures with CC/MCC and without CC/MCC, respectively) in MDC 13 (Diseases and Disorders of the Female Reproductive System). ICD–10–CM diagnosis code I86.2 (Pelvic varices) is reported to identify the condition of varicose veins in the pelvic region and is currently assigned to MDC 12 and to MDC 13. ICD–10–PCS procedure code 06LB3DZ (Occlusion of left renal vein with intraluminal device, percutaneous approach) may be reported to describe an embolization procedure performed for the treatment of pelvic varices and is currently assigned to MDC 5 (Diseases and Disorders of the Circulatory System) in MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively), MDC 6 (Diseases and Disorders of the Digestive System) in MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively), MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) in MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, CC, without CC/MCC, respectively), and MDC 24 (Multiple Significant Trauma) in MS–DRGs 957, 958, 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively). The requestor also noted that when this procedure is performed on the right renal vein (which is reported with ICD–10–PCS code 06L03DZ (Occlusion of inferior vena cava with intraluminal device, percutaneous approach) for varicose veins in the pelvic region, the case groups to MS–DRGs 715 and 716 and MS–DRGs 717 and 718 in MDC 12 (for male patients) or MS–DRGs 749 and 750 in MDC 13 (for female patients).

Our analysis of this grouping issue confirmed that when ICD–10–CM diagnosis code I86.2 (Pelvic varices) is reported with ICD–10–PCS procedure code 06LB3DZ, the case groups to MS–DRGs 981, 982, and 983. As noted above in previous discussions, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures.''

We examined the claims data to identify cases involving procedure code 06LB3DZ in MS–DRGs 981, 982, and 983 reported with a principal diagnosis code of I86.2. We found no cases in the claims data.

In the absence of data to examine, our clinical advisors reviewed this request and agree with the requestor that when the embolization procedure is performed on the left renal vein (reported with ICD–10–PCS procedure code 06LB3DZ), it should group to the same MS–DRGs as when it is performed on the right renal vein. Therefore, we are proposing to add ICD–10–PCS procedure code 06LB3DZ to MDC 12 in MS–DRGs 715, 716, 717, and 718 and to MDC 13 in MS–DRGs 749 and 750. Under this proposal, cases reporting ICD–10–CM diagnosis code I86.2 with ICD–10–PCS procedure code 06LB3DZ would group to MDC 12 (for male patients) or MDC 13 (for female patients).

13. Operating Room (O.R.) and Non-O.R. Issues

a. Background

Under the IPPS MS–DRGs (and former CMS MS–DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to the operating room, surgical patients were identified based on the procedures that were performed. Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.).

Currently, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS–DRG assignment

(''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non-O.R. affecting the MS–DRG.'' For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS–DRG, our clinical advisors recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures proposed to be newly designated as O.R. procedures. As discussed in section II.F.15. of the preamble of this proposed rule, we are making Table 6B.—New Procedure Codes—FY 2020 available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* We also refer readers to the ICD–10 MS–DRG Version 36 Definitions Manual at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS–DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

Given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. This will be a multi-year project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10. Therefore, we are again soliciting public comments on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration. Commenters should submit their recommendations to the following email address: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2019.

As a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R. procedures may warrant an O.R. type of designation. We intend to consider the resources used and how a procedure should affect the MS–DRG assignment. We may also consider the effect of specific surgical approaches to evaluate whether to subdivide specific MS–DRGs based on a specific surgical approach. We plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization.

We will provide more detail on this analysis and the methodology for conducting this review in future rulemaking. As we continue to develop our process and methodology, as noted above, we are soliciting public comments on other factors to consider in our refinement efforts to recognize and differentiate consumption of resources for the ICD–10 MS–DRGs.

In this proposed rule, we are addressing requests that we received regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures, or changing the designation from O.R. procedure to non-O.R. procedure. Below we discuss the process that was utilized for evaluating the requests that were received for FY 2020 consideration. For each procedure, our clinical advisors considered:

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or a nonextensive procedure; and
- To which MS–DRGs the procedure should be assigned.

We note that many MS–DRGs require the presence of any O.R. procedure. As a result, cases with a principal diagnosis associated with a particular MS–DRG would, by default, be grouped to that MS–DRG. Therefore, we do not list these MS–DRGs in our discussion below. Instead, we only discuss MS–DRGs that require explicitly adding the relevant procedures codes to the GROUPER logic in order for those procedure codes to affect the MS–DRG assignment as intended. In cases where we are proposing to change the designation of procedure codes from non-O.R. procedures to O.R. procedures, we also are proposing one or more MS–DRGs with which these procedures are clinically aligned and to which the procedure code would be assigned.

In addition, cases that contain O.R. procedures will map to MS–DRG 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRG 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. These procedures need not be assigned to MS–DRGs 981 through 989 in order for this to occur. Therefore, if requestors included some or all of MS–DRGs 981 through 989 in their request or included MS–DRGs that require the presence of any O.R. procedure, we did not specifically address that aspect in summarizing their request or our response to the request in the section below.

For procedures that would not typically require the resources of an operating room, our clinical advisors

determined if the procedure should affect the MS–DRG assignment.

We received several requests to change the designation of specific ICD–10–PCS procedure codes from non-O.R. procedures to O.R. procedures, or to change the designation from O.R. procedures to non-O.R. procedures. Below we detail and respond to some of those requests. With regard to the remaining requests, our clinical advisors believe it is appropriate to consider these requests as part of our comprehensive review of the procedure codes discussed above.

b. O.R. Procedures to Non-O.R. Procedures

(1) Bronchoalveolar Lavage

Bronchoalveolar lavage (BAL) is a diagnostic procedure in which a bronchoscope is passed through the patient's mouth or nose into the lungs. A small amount of fluid is squirted into an area of the lung and then collected for examination. Two requestors identified 13 ICD–10–PCS procedure codes describing BAL procedures that generally can be performed at bedside and would not require the resources of an operating room. In the ICD–10 MS–DRG Version 36 Definitions Manual, these 13 ICD–10–PCS procedure codes are currently recognized as O.R. procedures for purposes of MS–DRG assignment.

We agree with the requestors that these procedures do not typically require the resources of an operating room. Therefore, we are proposing to remove the following 13 procedure codes from the FY 2020 ICD–10 MS–DRGs Version 37 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this proposal, these procedures would no longer impact MS–DRG assignment.

ICD–10–PCS code	Code description
0B9H8ZX	Drainage of lung lingula, via natural or artificial opening endoscopic, diagnostic.
0B9K8ZX	Drainage of right lung, via natural or artificial opening endoscopic, diagnostic.
0B9L8ZX	Drainage of left lung, via natural or artificial opening endoscopic, diagnostic.
0B9M8ZX	Drainage of bilateral lungs, via natural or artificial opening endoscopic, diagnostic.
0B9C8ZZ	Drainage of right upper lung lobe, via natural or artificial opening endoscopic.
0B9D8ZZ	Drainage of right middle lung lobe, via natural or artificial opening endoscopic.
0B9F8ZZ	Drainage of right lower lung lobe, via natural or artificial opening endoscopic.
0B9G8ZZ	Drainage of left upper lung lobe, via natural or artificial opening endoscopic.
0B9H8ZZ	Drainage of Lung Lingula, via natural or artificial opening endoscopic.
0B9J8ZZ	Drainage of left lower lung lobe, via natural or artificial opening endoscopic.
0B9K8ZZ	Drainage of right lung, via natural or artificial opening endoscopic.
0B9L8ZZ	Drainage of left lung, via natural or artificial opening endoscopic.
0B9M8ZZ	Drainage of bilateral lungs, via natural or artificial opening endoscopic.

(2) Percutaneous Drainage of Pelvic Cavity

One requestor identified two ICD–10–PCS procedure codes that describe procedures involving percutaneous drainage of the pelvic cavity. The two ICD–10–PCS procedure codes are: 0W9J3ZX (Drainage of pelvic cavity, percutaneous approach, diagnostic) and 0W9J3ZZ (Drainage of pelvic cavity, percutaneous approach).

ICD–10–PCS procedure code 0W9J3ZX is currently recognized as an O.R. procedure for purposes of MS–DRG assignment, while the nondiagnostic ICD–10–PCS procedure code 0W9J3ZZ is not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor stated that percutaneous drainage procedures of the pelvic cavity for both diagnostic and nondiagnostic purposes are not complex procedures and both types of procedures are usually performed in a radiology suite. The requestor stated that both procedures should be classified as non-O.R. procedures.

We agree with the requestor that these procedures do not typically require the resources of an operating room. Therefore, we are proposing to remove procedure code 0W9J3ZX from the FY 2020 ICD–10 MS–DRG Version 37 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure. Under this proposal, this procedure would no longer impact MS–DRG assignment.

(3) Percutaneous Removal of Drainage Device

One requestor identified two ICD–10–PCS procedure codes that describe procedures involving the percutaneous placement and removal of drainage devices from the pancreas. These two ICD–10–PCS procedure codes are: 0FPG30Z (Removal of drainage device from pancreas, percutaneous approach) and 0F9G30Z (Drainage of pancreas with drainage device, percutaneous approach). ICD–10–PCS procedure code 0FPG30Z is currently recognized as an O.R. procedure for purposes of MS–DRG assignment, while ICD–10–PCS procedure code 0F9G30Z is not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor stated that percutaneous placement of drains is typically performed in a radiology suite under image guidance and removal of a drain would not be more resource intensive than its placement.

We agree with the requestor that these procedures do not typically require the resources of an operating room. Therefore, we are proposing to remove ICD–10–PCS procedure code 0FPG30Z from the FY 2020 ICD–10 MS–DRG Version 37 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure. Under this proposal, this procedure would no longer impact MS–DRG assignment.

c. Non-O.R. Procedures to O.R. Procedures

(1) Percutaneous Occlusion of Gastric Artery

One requestor identified two ICD–10–PCS procedure codes that describe percutaneous occlusion and restriction of the gastric artery with intraluminal device, ICD–10–PCS procedure codes 04L23DZ (Occlusion of gastric artery with intraluminal device, percutaneous approach) and 04V23DZ (Restriction of gastric artery with intraluminal device, percutaneous approach), that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor noted that transcatheter endovascular embolization of the gastric artery with intraluminal devices uses comparable resources to transcatheter endovascular embolization of the gastroduodenal artery. The requestor stated that ICD–10–PCS procedure codes 04L33DZ (Occlusion of hepatic

artery with intraluminal device, percutaneous approach) and 04V33DZ (Restriction of hepatic artery with intraluminal device, percutaneous approach) are recognized as O.R. procedures for purposes of MS–DRG assignment, and ICD–10–PCS procedure codes 04L23DZ and 04V23DZ should therefore also be recognized as O.R. procedures for purposes of MS–DRG assignment. We note that, contrary to the requestor's statement, ICD–10–PCS procedure code 04V23DZ is already recognized as an O.R. procedure for purposes of MS–DRG assignment.

We agree with the requestor that ICD–10–PCS procedure code 04L23DZ typically requires the resources of an operating room. Therefore, we are proposing to add this code to the FY 2020 ICD–10 MS–DRG Version 37 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure assigned to MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, CC, without CC/MCC, respectively) in MDC 05 (Diseases and Disorders of the Circulatory System); MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures, with MCC, CC, without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, CC, without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, CC, without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma).

(2) Endoscopic Insertion of Endobronchial Valves

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41257), we discussed a comment we received in response to the FY 2019 IPPS/LTCH PPS proposed rule regarding eight ICD–10–PCS procedure codes that describe endobronchial valve procedures that the commenter believed should be designated as O.R. procedures. The codes are identified in the following table.

ICD–10–PCS code	Code description
0BH38GZ	Insertion of endobronchial valve into right main bronchus, via natural or artificial opening endoscopic.
0BH48GZ	Insertion of endobronchial valve into right upper lobe bronchus, via natural or artificial opening endoscopic.
0BH58GZ	Insertion of endobronchial valve into right middle lobe bronchus, via natural or artificial opening endoscopic.
0BH68GZ	Insertion of endobronchial valve into right lower lobe bronchus, via natural or artificial opening endoscopic.
0BH78GZ	Insertion of endobronchial valve into left main bronchus, via natural or artificial opening endoscopic.
0BH88GZ	Insertion of endobronchial valve into left upper lobe bronchus, via natural or artificial opening endoscopic.
0BH98GZ	Insertion of endobronchial valve into lingula bronchus, via natural or artificial opening endoscopic.
0BHB8GZ	Insertion of endobronchial valve into left lower lobe bronchus, via natural or artificial opening endoscopic.

The commenter stated that these procedures are most commonly performed in the O.R., given the need for better monitoring and support through the process of identifying and occluding a prolonged air leak using endobronchial valve technology. The commenter also noted that other endobronchial valve procedures have an O.R. designation. We noted that, in the ICD–10 MS–DRGs Version 35, these eight ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. The commenter requested that these eight procedure codes be assigned to MS–DRG 163 (Major Chest Procedures with MCC) due to similar cost and resource use. As discussed in the FY 2019 IPPS/LTCH PPS final rule, our clinical advisors disagreed with the commenter that the eight identified procedures typically require the use of an operating room, and believed that these procedures would typically be performed in an endoscopy suite. Therefore, we did not finalize a change to the eight procedure codes describing endoscopic insertion of an endobronchial valve listed in the table above for FY 2019 under the ICD–10 MS–DRGs Version 36.

After publication of the FY 2019 IPPS/LTCH PPS final rule, we received feedback from several stakeholders expressing continued concern with the designation of the eight ICD–10–PCS procedure codes describing the endoscopic insertion of an endobronchial valve listed in the table above, including requests to reconsider the designation of these codes for FY 2020. Some requestors stated that while they appreciated CMS' attention to the issue, they believed that important clinical and financial factors had been overlooked. The requestors noted that while the site of care is an important consideration for MS–DRG assignment, there are other clinical factors such as case complexity, patient health risk and the need for anesthesia that also affect hospital resource consumption and should influence MS–DRG assignment. With regard to complexity, the requestors stated that many of these patients are high-risk, often recovering from major lung surgery and have significantly compromised respiratory function. According to one requestor, these patients may have major comorbidities, such as cancer or emphysema contributing to longer lengths of stay in the hospital. This requestor acknowledged that procedures performed for the endoscopic insertion of an endobronchial valve are often, but not always, performed in the O.R., however, the requestor also noted this should not preclude the designation of these procedures as O.R. procedures since there have been other examples of reclassification requests where the combination of factors, such as treatment difficulty, resource utilization, patient health status, and anesthesia administration were considered in the decision to change the designation for a procedure from non-O.R. to O.R. Another requestor stated that CMS' current designation of a procedure involving the endoscopic insertion of an endobronchial valve as a non-O.R. procedure is not reflective of actual practice and this designation has payment consequences that may affect access to the treatment for a vulnerable patient population, with limited treatment options. The requestor recommended that procedures involving the endoscopic insertion of an endobronchial valve should be designated as O.R. procedures and assigned to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC and without CC/MCC, respectively). In addition, a few of the requestors also conducted their own analyses and indicated that if procedures involving the endoscopic insertion of an endobronchial valve were to be assigned to MS–DRGs 163, 164, and 165, the average costs of the cases reporting a procedure code describing the endoscopic insertion of an endobronchial valve would still be higher compared to all the cases in the assigned MS–DRG.

We examined claims data from the September 2018 update of the FY 2018 MedPAR file for MS–DRGs 163, 164 and

165 to identify cases reporting any one of the eight procedure codes listed in the above table describing the endoscopic insertion of an endobronchial valve. Cases reporting one of these procedure codes would be assigned to MS–DRG 163, 164, or 165 if at least one other procedure that is designated as an O.R. procedure and assigned to these MS–DRGs was also reported on the claim. In addition, cases reporting a procedure code describing the endoscopic insertion of an endobronchial valve with a different surgical approach are assigned to MS–DRGs 163, 164, and 165. Our findings are shown in the following table.

MS–DRGs FOR MAJOR CHEST PROCEDURES WITH ENDOSCOPIC INSERTION OF ENDOBRONCHIAL VALVE PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 163—All cases	10,812	11.6	$33,433
MS–DRG 163—Cases reporting a procedure for the endoscopic insertion of an endobronchial valve	49	21.1	53,641
MS–DRG 164—All cases	14,800	5.6	18,202
MS–DRG 164—Cases reporting a procedure for the endoscopic insertion of an endobronchial valve	23	14	37,287
MS–DRG 165—All cases	7,907	3.3	13,408
MS–DRG 165—Cases reporting a procedure for the endoscopic insertion of an endobronchial valve	3	18.3	39,249

We found a total of 10,812 cases in MS–DRG 163 with an average length of stay of 11.6 days and average costs of $33,433. Of those 10,812 cases, we found 49 cases reporting a procedure for the endoscopic insertion of an endobronchial valve with an average length of stay of 21.1 days and average costs of $53,641. For MS–DRG 164, we found a total of 14,800 cases with an average length of stay of 5.6 days and average costs of $18,202. Of those 14,800 cases, we found 23 cases reporting a procedure for the endoscopic insertion of an endobronchial valve with an average length of stay of 14 days and average costs of $37,287. For MS–DRG 165, we found a total of 7,907 cases with an average length of stay of 3.3 days and average costs of $13,408. Of those 7,907 cases, we found 3 cases reporting a procedure for the endoscopic insertion of an endobronchial valve with an average length of stay of 18.3 days and average costs of $39,249.

We also examined claims data to identify any cases reporting any one of the eight procedure codes listed in the table above describing the endoscopic insertion of an endobronchial valve within MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). Cases reporting one of these procedure codes would be assigned to MS–DRG 166, 167, or 168 if at least one other procedure that is designated as an O.R. procedure and assigned to these MS–DRGs was also reported on the claim. In addition, MS–DRGs 166, 167, and 168 are the other surgical MS–DRGs where cases reporting a respiratory diagnosis within MDC 4 would be assigned. Our findings are shown in the following table.

MS–DRGs FOR OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH ENDOSCOPIC INSERTION OF ENDOBRONCHIAL VALVE

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 166—All cases	16,050	10.6	$26,645
MS–DRG 166—Cases reporting a procedure for the endoscopic insertion of an endobronchial valve	11	25.7	71,700
MS–DRG 167—All cases	8,165	5.3	13,687
MS–DRG 167—Cases reporting a procedure for the endoscopic insertion of an endobronchial valve	4	10	28,847
MS–DRG 168—All cases	2,430	2.8	9,645

We found a total of 16,050 cases in MS–DRG 166 with an average length of stay of 10.6 days and average costs of $26,645. Of those 16,050 cases, we found 11 cases reporting a procedure for the endoscopic insertion of an endobronchial valve with an average length of stay of 25.7 days and average costs of $71,700. For MS–DRG 167, we found a total of 8,165 cases with an average length of stay of 5.3 days and average costs of $13,687. Of those 8,165 cases, we found 4 cases reporting a procedure for the endoscopic insertion of an endobronchial valve with an average length of stay of 10 days and average costs of $28,847. For MS–DRG 168, we found a total of 2,430 cases with an average length of stay of 2.8 days and average costs of $9,645. Of those 2,430 cases, we did not find any cases reporting a procedure for the endoscopic insertion of an endobronchial valve.

The results of our data analysis indicate that cases reporting a procedure for the endoscopic insertion of an endobronchial valve in MS–DRGs 163, 164, 165, 166, and 167 have a longer length of stay and higher average costs when compared to all the cases in their assigned MS–DRG. Because the data are based on surgical MS–DRGs 163, 164, 165, 166 and 167, and the procedure codes for endoscopic insertion of an endobronchial valve are currently designated as non-O.R. procedures, there was at least one other O.R. procedure reported on the claim resulting in case assignment to one of those MS–DRGs. Our clinical advisors indicated that because there was another O.R. procedure reported, the insertion of the endobronchial valve procedure may or may not have been

the main determinant of resource use for those cases. Therefore, we conducted further analysis to evaluate cases for which no other O.R. procedure was performed with the endoscopic insertion of an endobronchial valve and case assignment resulted in a medical MS–DRG. Our findings are shown in the following table.

MEDICAL MS–DRGS WITH INSERTION OF ENDOBRONCHIAL VALVE PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 069 (Transient Ischemia without Thrombolytic)	1	9	$26,002
MS–DRG 177 (Respiratory Infections and Inflammations with MCC)	11	19.5	33,877
MS–DRG 178 (Respiratory Infections and Inflammations with CC)	4	10.8	20,109
MS–DRG 180 (Respiratory Neoplasms with MCC)	2	11.5	19,273
MS–DRG 181 (Respiratory Neoplasms with MCC)	1	3	12,641
MS–DRG 186 (Pleural Effusion with MCC)	1	8	23,609
MS–DRG 187 (Pleural Effusion with CC)	1	18	49,214
MS–DRG 189 (Pulmonary Edema and Respiratory Failure)	2	13.5	65,431
MS–DRG 190 (Chronic Obstructive Pulmonary Disease with MCC)	2	9	39,925
MS–DRG 191 (Chronic Obstructive Pulmonary Disease with CC)	1	15	55,958
MS–DRG 192 (Chronic Obstructive Pulmonary Disease without CC/MCC)	1	5	10,394
MS–DRG 193 (Simple Pneumonia and Pleurisy with MCC)	1	18	27,182
MS–DRG 197 (Interstitial Lung Disease with CC)	1	12	11,458
MS–DRG 199 (Pneumothorax with MCC)	28	16.4	38,384
MS–DRG 200 (Pneumothorax with CC)	11	8.3	20,764
MS–DRG 201 (Pneumothorax without CC/MCC)	2	10	20,243
MS–DRG 205 (Other Respiratory System Diagnoses with MCC)	2	4.5	10,851
MS–DRG 207 (Respiratory System Diagnosis with Ventilation Support >96 Hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO))	4	20	67,299
MS–DRG 208 (Respiratory System Diagnosis with Ventilation Support ≦96 Hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO))	8	13.6	32,533
MS–DRG 815 (Reticuloendothelial and Immunity Disorders with CC)	1	5	17,379
MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours with MCC)	3	15	39,706
MS–DRG 919 (Complications of Treatment with MCC)	2	5	36,143
MS–DRG 920 (Complications of Treatment with CC)	1	5	14,923
Total	91	13.7	33,377

The data indicate that there is a wide variation in the average length of stay and average costs for cases reporting a procedure for the endoscopic insertion of an endobronchial valve, with volume generally low across MS–DRGs. As shown in the table, for several of the medical MS–DRGs, there was only one case reporting a procedure for the endoscopic insertion of an endobronchial valve. The highest volume of cases reporting a procedure for the endoscopic insertion of an endobronchial valve was found in MS–DRG 199 (Pneumothorax with MCC) with a total of 28 cases with an average length of stay of 16.4 days and average costs of $38,384. The highest average costs and longest average length of stay for cases reporting a procedure for the endoscopic insertion of an endobronchial valve was $67,299 in MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support >96 Hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO)) where 4 cases were found with an average length of stay of 20 days. Overall, there was a total of 91 cases reporting the insertion of an endobronchial valve procedure with an average length of stay of 13.7 days and average costs of $33,377 across the medical MS–DRGs.

Our clinical advisors agree that the subset of patients who undergo endoscopic insertion of an endobronchial procedure are complex and may have multiple comorbidities such as severe underlying lung disease that impact the hospital length of stay. They also believe that, as we begin the process of refining how procedure codes may be classified under ICD–10–PCS, including designation of a procedure as O.R. or non-O.R., we should take into consideration whether the procedure is driving resource use for the admission. (We refer the reader to section II.F.13.a. of the preamble of this proposed rule for the discussion of our plans to conduct a comprehensive review of the ICD–10–PCS procedure codes). Based on the claims data analysis, which show a wide variation in average costs for cases reporting endoscopic insertion of an endobronchial valve without an O.R. procedure, our clinical advisors are not convinced that endoscopic insertion of an endobronchial valve is a key contributing factor to the consumption of resources as reflected in the data. They also believe, in review of the procedures that are currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168, that further refinement of these MS–DRGs may be warranted. For these reasons, at this time, our clinical advisors do not support designating endoscopic insertion of an endobronchial valve as an O.R. procedure, nor do they support assignment of these procedures to MS–DRGs 163, 164, and 165 until additional analyses can be performed for this subset of patients as part of the comprehensive procedure code review.

For the reasons described above, we are not proposing to change the current non-O.R. designation of the eight ICD–10–PCS procedure codes that describe endoscopic insertion of an endobronchial valve. However, because we agree that endoscopic insertion of an endobronchial valve procedures are performed on clinically complex patients, we believe it may be appropriate to consider designating these procedures as non-O.R. affecting specific MS–DRGs for FY 2020. Therefore, we are requesting public comment on designating these procedure codes as non-O.R. procedures affecting the MS–DRG assignment, including the specific MS–DRGs that cases reporting the endoscopic insertion

of an endobronchial valve should affect for FY 2020. As noted, it is not clear based on the claims data to what degree the endoscopic insertion of an endobronchial valve is a contributing factor for the consumption of resources for these clinically complex patients and given the potential refinement that may be needed for MS–DRGs 163, 164, 165, 166, 167, and 168, we are soliciting comment on whether cases reporting the endoscopic insertion of an endobronchial valve should affect any of these MS–DRGs or other MS–DRGs.

14. Proposed Changes to the MS–DRG Diagnosis Codes for FY 2020

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (non-CC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as an MCC, a CC, or a non-CC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since this comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when receiving requests to change the severity level of specific diagnosis codes. However, given the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since this review, we believe it is necessary to conduct a comprehensive analysis once again. We have completed this analysis and we are discussing our findings in this proposed rule. We used the same methodology utilized in FY 2008 to conduct this analysis, as described below.

For each secondary diagnosis, we measured the impact in resource use for the following three subsets of patients:

(1) Patients with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs.

(2) Patients with at least one other secondary diagnosis that is a CC but none that is an MCC.

(3) Patients with at least one other secondary diagnosis that is an MCC.

Numerical resource impact values were assigned for each diagnosis as follows:

Value	Meaning
0	Significantly below expected value for the non-CC subgroup.
1	Approximately equal to expected value for the non-CC subgroup.
2	Approximately equal to expected value for the CC subgroup.
3	Approximately equal to expected value for the MCC subgroup.
4	Significantly above the expected value for the MCC subgroup.

Each diagnosis for which Medicare data were available was evaluated to determine its impact on resource use and to determine the most appropriate CC subclass (non-CC, CC, or MCC) assignment. In order to make this determination, the average cost for each subset of cases was compared to the expected cost for cases in that subset. The following format was used to evaluate each diagnosis:

Code	Diagnosis	Cnt1	C1	Cnt2	C2	Cnt3	C3

Count (Cnt) is the number of patients in each subset and C1, C2, and C3 are a measure of the impact on resource use of patients in each of the subsets. The C1, C2, and C3 values are a measure of the ratio of average costs for patients with these conditions to the expected average cost across all cases. The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is a major CC. The C3 value reflects a patient with at least one other secondary diagnosis that is a major CC. A value close to 1.0 in the C1 field would suggest that the code produces the same expected value as a non-CC diagnosis. That is, average costs for the case are similar to the expected average costs for that subset and the diagnosis is not expected to increase resource usage. A higher value in the C1 (or C2 and C3) field suggests more resource usage is associated with the diagnosis and an increased likelihood that it is more like a CC or major CC than a non-CC. Thus, a value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. A value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or non-CC. For example, a C1 value of 1.8 for a secondary diagnosis means that for the subset of patients who have the secondary diagnosis and have either no other secondary diagnosis present, or all the other secondary diagnoses present are non-CCs, the impact on resource use of the secondary diagnoses is greater than the expected value for a non-CC by an amount equal to 80 percent of the difference between the expected value of a CC and a non-CC (that is, the impact on resource use of the secondary diagnosis is closer to a CC than a non-CC).

These mathematical constructs are used as guides in conjunction with the judgment of our clinical advisors to classify each secondary diagnosis reviewed as an MCC, a CC, or a non-CC. Our clinical advisors reviewed the resource use impact reports and suggested modifications to the initial CC subclass assignments when clinically appropriate.

c. Proposed Changes to Severity Levels

(1) Summary of Proposed Changes

The diagnosis codes for which we are proposing a change in severity level designation as a result of the analysis

described in this proposed rule are shown in Table 6P.1c. (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). Using the method described above to perform our comprehensive CC/MCC analysis, our clinical advisors recommended a change in the severity level designation for 1,492 ICD–10–CM diagnosis codes. As shown in Table 6P.1c. associated with this proposed rule, the proposed changes to severity level resulting from our comprehensive analysis would move some diagnosis codes to a higher severity level designation and other diagnosis codes to a lower severity level designation, as indicated in the two columns which display CMS' FY 2019 classification in column C and the proposed changes for FY 2020 in column D.

The table below shows the Version 36 ICD–10 MS–DRG categorization of diagnosis codes by severity level.

CURRENT CATEGORIZATION OF CC CODES

[Version 36]

	Number of codes
MCC	3,244
CC	14,528
Non-CC	54,160
Total	71,932

The following table compares the Version 36 ICD–10 MS–DRG CC list and the proposed Version 37 ICD–10 MS–DRG CC list. There are 17,772 diagnosis codes on the Version 36 MCC/CC lists. The proposed MCC/CC severity level changes would reduce the number of diagnosis codes on the MCC/CC lists to 16,790 (3,099 + 13,691). Based on the Version 36 MCC/CC lists, 81.5 percent of cases have at least one MCC/CC present, using claims data from the September 2018 update of the FY 2018 MedPAR file. Based on the proposed Version 37 MCC/CC lists, the percent of cases having at least one MCC/CC present would be reduced to 76.6 percent.

COMPARISON OF CURRENT CC LIST AND PROPOSED CC LIST

	Current CC List	Proposed CC List
Codes designated as an MCC	3,244	3,099
Percent of cases with one or more MCCs	41.0%	36.3%
Average charge of cases with one or more MCCs	$16,439	$16,490
Codes designated as a CC	14,528	13,691
Percent of cases with one or more CCs	40.5%	40.3%
Average charge of cases with one or more CCs	$10,332	$10,518
Codes designated as non-CC	54,160	55,142
Percent of cases with no CC	18.5%	23.4%
Average charge of cases with no CCs	$9,885	$10,166

Using the method described above to perform our comprehensive analysis, we are proposing to modify the Version 36 CC subclass assignments for 2.1 percent of the ICD–10–CM diagnosis codes, as summarized in the table below.

PROPOSED MCC/CC SUBCLASS MODIFICATIONS

Severity level—CC subclass	Version 36 severity level number of codes	Proposed version 37 severity level number of codes	Percent change	Proposed version 37 change to MCC subclass, number of codes	Proposed version 37 change to CC subclass, number of codes	Proposed Version 37 change to non-CC subclass, number of codes
MCC	3,244	3,099	−4.5	N/A	136	17
CC	14,528	13,691	−5.8	8	N/A	1,148
Non-CC	54,160	55,142	1.8	0	183	N/A
Total	71,932	71,932	N/A	8	319	1,166

As a result of these proposed changes, of the 71,932 diagnosis codes included in the analysis, the net result would be a decrease of 145 (3,244–3,099) codes designated as an MCC, a decrease of 837 (14,528 − 13,691) codes designated as a CC, and an increase of 982 (55,142–54,160) codes designated as a non-CC.

(2) Illustrations of Proposed Severity Level Changes

As noted above, based on our comprehensive CC/MCC analysis as described previously in this section, we are proposing changes in the severity level designations for 1,492 ICD–10–CM diagnosis codes, and the specific proposed changes to severity level designations for those diagnosis codes are shown in Table 6P.1.c. associated with this proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). Below we provide illustrative examples of certain categories of codes for which we are proposing changes to the severity level designations as a result of our comprehensive analysis. As described above, these proposals are based on review of the data as well as consideration of the clinical nature of each of the secondary diagnoses and the severity level of clinically similar diagnoses. The first set of codes, from the Neoplasms chapter, encompasses more than half of all proposed severity level changes. The additional examples are from a variety of body systems and conditions, and they are illustrative of both proposed increases and proposed decreases in severity level designation. We note that we are making available a

supplementary file containing the data describing the impact on resource use when reported as a secondary diagnosis for all 1,492 ICD–10–CM diagnosis codes for which we are proposing a change in designation via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

(a) Neoplasms Chapter Codes

Of the total number of ICD–10–CM diagnosis codes for which we are proposing a change of severity level designation, 767 are from the Neoplasms chapter of the ICD–10–CM classification (C00–D49) and are currently designated as a CC. We note that the Neoplasms chapter contains a total of 1,661 ICD–10–CM diagnosis codes. In Version 36 of the MS–DRGs, none of the 1,661 neoplasm codes are designated as an MCC, 767 are designated as a CC, and 894 are designated as a non-CC. For all 767 codes currently designated as a CC, our clinical advisors recommended changing the severity level designation from CC to non-CC. The following table presents examples of some of the neoplasm codes for which we are proposing a severity level change to non-CC, and their impact on resource use when reported as a secondary diagnosis. As noted previously, the data analysis for the remainder of these neoplasm codes is included in the supplementary file that we are making available on the CMS website.

PROPOSED SEVERITY LEVEL CHANGES FOR NEOPLASM CODES AS SECONDARY DIAGNOSIS

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
C20 (Malignant neoplasm of rectum).	2,960	1.0485	7,561	2.2169	6,492	3.0790	CC	Non-CC.
C22.0 (Liver cell carcinoma)	1,672	1.2289	9,444	2.0638	12,503	3.0914	CC	Non-CC.
C25.0 (Malignant neoplasm of head of pancreas).	1,205	1.1357	3,834	2.1788	6,191	3.0229	CC	Non-CC.
C64.1 (Malignant neoplasm of right kidney, except renal pelvis).	1,512	1.2276	4,463	2.1600	4,593	3.1158	CC	Non-CC.
C64.2 (Malignant neoplasm of left kidney, except renal pelvis).	1,368	1.3407	4,517	2.1947	4,593	3.0947	CC	Non-CC.
C78.01 (Secondary malignant neoplasm of right lung).	4,149	1.0417	14,946	2.0888	20,324	3.0043	CC	Non-CC.
C78.02 (Secondary malignant neoplasm of left lung).	3,599	1.0078	13,456	2.0853	18,384	3.0024	CC	Non-CC.
C79.31 (Secondary malignant neoplasm of brain).	7,164	1.1895	22,989	2.1330	41,387	2.9116	CC	Non-CC.
C79.51 (Secondary malignant neoplasm of bone).	26,095	1.3048	88,022	2.2020	99,670	3.0449	CC	Non-CC.
C90.00 (Multiple myeloma not having achieved remission).	9,947	1.1588	34,155	2.2144	33,830	3.1281	CC	Non-CC.

As described in section II.F.15.b. of the preamble of this proposed rule, we examined the impact in resource use for three subsets of patients in order to evaluate the severity level designations for each secondary diagnosis. In the table above, the C1 values are generally close to 1, C2 values are generally close to 2, and C3 values are generally close to 3. As explained in section II.F.15.b. of the preamble of this proposed rule, these values suggest that when a neoplasm is reported as a secondary diagnosis, the resources involved in caring for a patient with this condition are more aligned with a non-CC severity level than a CC severity level. Our clinical advisors reviewed these data and believe the resources involved in caring for a patient with this condition are more aligned with a non-CC severity level. Our clinical advisors noted that when a neoplasm is reported as a secondary diagnosis, because it is not the condition that occasioned the patient's admission to the hospital, it does not significantly impact resource use. Our clinical advisors noted that if these patients are admitted for treatment of the neoplasm, the neoplasm is the principal diagnosis, and other complicating or comorbid conditions reported as secondary diagnoses would determine the appropriate severity level designation for each particular case. For example, if a patient is admitted for resection of malignant neoplasm of the right kidney, ICD–10–CM diagnosis code C64.1 (Malignant neoplasm of right kidney, except renal pelvis) is reported as the principal diagnosis, and any complicating conditions reported as secondary diagnoses during the hospital stay would determine the appropriate severity level designation for the case.

(b) Diseases of the Circulatory System Chapter Codes

In the Diseases of the Circulatory System chapter of the ICD–10–CM diagnosis classification (I00–I99), based on the results of our comprehensive review, we are proposing to change the severity level designation for 13 ICD–10–CM diagnosis codes from categories I21 (Acute myocardial infarction) and I22 (Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction) from an MCC to a CC.

The following table contains the ICD–10–CM diagnosis codes for which we are proposing a severity level change, and their impact on resource use when reported as a secondary diagnosis.

PROPOSED SEVERITY LEVEL CHANGES FOR MYOCARDIAL INFARCTION CODES AS SECONDARY DIAGNOSIS

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
I21.01 (ST elevation (STEMI) myocardial infarction involving left main coronary artery).	2	1.2010	17	2.9902	38	3.0195	MCC	CC.
I21.02 (ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery).	149	0.9326	322	1.6565	754	3.3157	MCC	CC.
I21.09 (ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall).	583	1.2201	1,288	2.2225	3,744	3.1094	MCC	CC.
I21.11 (ST elevation (STEMI) myocardial infarction involving right coronary artery).	175	1.8486	326	2.0867	581	3.1141	MCC	CC.
I21.19 (ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall).	913	1.5054	1,940	2.2641	4,081	3.1996	MCC	CC.
I21.21 (ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery).	30	0.9445	56	2.4160	117	2.9965	MCC	CC.
I21.29 (ST elevation (STEMI) myocardial infarction involving other sites).	162	1.0143	417	2.2401	1,048	3.3341	MCC	CC.
I21.3 (ST elevation (STEMI) myocardial infarction of unspecified site).	1,271	1.6587	3,876	2.2420	10,168	3.2432	MCC	CC.
I22.0 (Subsequent ST elevation (STEMI) myocardial infarction of anterior wall).	10	0.9199	74	1.2558	165	2.6794	MCC	CC.
I22.1 (Subsequent ST elevation (STEMI) myocardial infarction of inferior wall).	4	0.0000	81	1.6022	143	3.3056	MCC	CC.
I22.2 (Subsequent non-ST elevation (NSTEMI) myocardial infarction).	94	2.1034	352	2.1291	1,916	3.0157	MCC	CC.
I22.8 (Subsequent ST elevation (STEMI) myocardial infarction of other sites).	5	2.2963	18	2.0589	53	3.1306	MCC	CC.
I22.9 (Subsequent ST elevation (STEMI) myocardial infarction of unspecified site).	27	1.7140	87	1.8737	293	2.9627	MCC	CC.

As shown in the table above, all of these myocardial infarction codes are currently assigned as MCCs. As explained earlier, values close to 2.0 in column C1 suggest that the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C1 values for the secondary diagnoses with the largest number of cases in this subset in the table above, ICD–10–CM codes I21.3 and I21.19, are closer to 2.0 than to 1.0, indicating that these secondary diagnoses are more aligned with a CC than either a non-CC or an MCC. Therefore, the data suggest that for patients for whom any of the myocardial infarction codes listed in the table above is reported as a secondary diagnosis, the resources involved in their care are not aligned with those of an MCC. Our clinical advisors reviewed these data and believe that the resources involved in caring for a patient with this condition are aligned with a CC. Patients with a secondary diagnosis of myocardial infarction may require additional diagnostic imaging, monitoring, medications, and additional interventions, thereby consuming resources that are consistent with CC status. Our clinical advisors noted that while, for certain codes, the number of cases shown in the data may not be sufficient to reliably indicate impact on resource use as a secondary diagnosis, these codes are clinically similar to other codes for which the data are sufficient to indicate impact on resource use. Because our clinical advisors believe that it is appropriate to ensure consistency across codes describing similar diagnoses, we are proposing to reassign the severity level for all of the codes in the table above from an MCC to a CC.

(c) Diseases of the Skin and Subcutaneous Tissue Chapter Codes

In the Diseases of the Skin and Subcutaneous Tissue chapter of the ICD–10–CM diagnosis classification (L00–L99), based on the results of our comprehensive review, we are proposing a change to the severity level for 150 ICD–10–CM diagnosis codes describing pressure ulcers. Pressure ulcers, which are also known as pressure injuries, involve damage to the skin and soft tissue. They may result from prolonged pressure over a bony prominence or result from a medical device. The ICD–10–CM classification includes 150 diagnosis codes that describe pressure ulcers across various anatomical regions and across the various possible stages (stages 1 through 4, unspecified stage, and unstageable). These codes are listed in Table 6P.1.d. associated with this proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). In the course of our comprehensive review of the CC/MCC lists, our clinical advisors reviewed the current categorization of pressure ulcers, which designate all stage 3 and 4 pressure ulcers as MCCs, while stage 1, stage 2, unspecified stage,

and unstageable pressure ulcers are currently designated as non-CCs.

Our clinical advisors reviewed data on the relative contribution to the overall cost of hospital care for all stages of pressure ulcers coded as secondary diagnoses, and found (1) that there was little difference in the cost contribution regardless of stage, and (2) the cost contributions (cost weights) of all stages supported a designation of CC rather than MCC (for stage 3 and 4 ulcers), and CC rather than non-CC (for stages 1, 2, unspecified, and unstageable). Our clinical advisors noted that the apparent similar contribution of all pressure ulcer stages can be explained by the fact that pressure ulcers occur in patients with serious underlying illness, such as stroke, cancer, dementia, and end-stage cardiac or pulmonary disease that can result in multiple factors (frailty, immobility, paralysis, malnutrition, and general debility) that predispose them to pressure ulcers. It is the serious underlying illness and debilitated state that causes the pressure ulcer that is the primary driver of resource use. Although a pressure ulcer at any stage requires care and preventive measures that make additional contributions to the overall cost of care, our clinical advisors believe that the fact that the ulcer developed in the first place is more important than the stage of the ulcer itself in determining the impact on the costs of hospitalization. The presence of a pressure ulcer may indicate an increase in resource use, but that increase is similar regardless of the stage of the ulcer.

The following table contains illustrations of pressure ulcer codes and their impact on resource use when reported as a secondary diagnosis. We selected secondary diagnosis codes describing pressure ulcer of the sacrum as examples because they account for almost half of all instances of pressure ulcers reported as secondary diagnoses, but note that the data for the codes describing pressure ulcer of other body parts generally show a similar pattern. As noted previously, the data analysis for the remainder of the pressure ulcer codes for which we are proposing a change in severity level designation is included in the supplementary file that we are making available on the CMS website.

PROPOSED SEVERITY LEVEL CHANGES FOR PRESSURE ULCER CODES AS SECONDARY DIAGNOSIS

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
L89.150 (Pressure ulcer of sacral region, unstageable).	605	2.003	6,247	2.560	24,047	3.254	Non-CC	CC.
L89.151 (Pressure ulcer of sacral region, stage 1).	2,374	1.691	16,688	2.404	36,428	3.182	Non-CC	CC.
L89.152 (Pressure ulcer of sacral region, stage 2).	4,238	1.737	35,608	2.497	95,832	3.274	Non-CC	CC.
L89.153 (Pressure ulcer of sacral region, stage 3).	1,722	1.832	15,266	2.522	48,414	3.289	MCC	CC.
L89.154 (Pressure ulcer of sacral region, stage 4).	1,237	1.755	14,306	2.438	56,619	3.196	MCC	CC.
L89.159 (Pressure ulcer of sacral region, unspecified stage).	1,453	1.387	12,466	2.311	35,020	3.176	Non-CC	CC.

As explained previously, a value in column C1 that is close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. Given that the values in column C1 in the table above are closer to 2.0 than to 1.0, the data suggest that when pressure ulcers of the sacral region are reported as a secondary diagnosis, the resources involved in caring for these patients are more consistent with a CC than either a non-CC or an MCC. Our clinical advisors reviewed these data and believe that it is appropriate to ensure consistency across codes involving similar diagnoses. Therefore, we are proposing to designate as CCs both the 50 ICD–10–CM diagnosis codes that are currently designated as MCCs and the 100 ICD–10–CM diagnosis codes currently designated as non-CCs.

We note that, under the Hospital-Acquired Condition (HAC) payment provision established by section 5001(c) of the Deficit Reduction Act (DRA) of 2005, hospitals no longer receive additional payment for cases in which one of the selected conditions occurred but was not present on admission (POA). That is, the case is paid as though the condition were not present. The HAC–POA payment provision is applicable for secondary diagnosis code reporting only, as the selected conditions are designated as a CC or an MCC when reported as a secondary diagnosis. For the DRA HAC–POA payment provision, a payment adjustment is only applicable if there are no other CC/MCC conditions reported on the claim. Currently, there are 14 HAC categories subject to the HAC–POA payment provision, one of which is pressure ulcers. The pressure ulcer HAC category (HAC 04) specifically includes diagnosis codes describing a stage 3 or stage 4 pressure ulcer because they are designated as an MCC, as noted earlier in this section. If the proposed severity level designations for the pressure ulcer diagnosis codes are finalized, the 100 ICD–10–CM diagnosis codes describing pressure ulcers currently designated as non-CCs would be subject to the HAC–POA payment provision as CCs when reported as a secondary diagnosis and not POA, effective beginning in FY 2020. The diagnosis codes describing a stage 3 or stage 4 pressure ulcer would continue to be subject to the HAC–POA payment provision as CCs.

In addition, consistent with the proposed changes to the severity level designation of the pressure ulcer codes, we are proposing to revise the title of the HAC 04 category from ''Pressure Ulcer—Stages III & IV'' to ''Pressure Ulcers''. We refer readers to the website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html* for additional information regarding the HAC–POA payment provision under the DRA.

(d) Diseases of the Genitourinary System Chapter Codes

In the Diseases of the Genitourinary System chapter of the ICD–10–CM diagnosis classification (N00–N99), based on the results of our comprehensive analysis, we are proposing to change the severity level designation for eight ICD–10–CM diagnosis codes. For these eight

diagnosis codes, based on their clinical judgment and for the reasons described below, our clinical advisors recommended that we increase the severity level designation from a CC to an MCC for one code, and from a non-CC to a CC for seven codes. The following table contains the Diseases of the Genitourinary System chapter codes that describe conditions for which we are proposing a severity level designation change, and their impact on resource use when reported as a secondary diagnosis.

PROPOSED SEVERITY LEVEL CHANGES FOR GENITOURINARY CODES AS SECONDARY DIAGNOSIS

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
N10 (Acute pyelonephritis)	5,385	0.9639	20,476	1.9444	26,929	3.0413	Non-CC	CC.
N18.4 (Chronic kidney disease, stage 4 (severe)).	36,940	1.0919	219,482	2.0679	319,849	3.0840	Non-CC	CC.
N18.5 (Chronic kidney disease, stage 5).	1,158	1.0303	30,851	2.0841	34,733	3.1508	Non-CC	CC.
N18.6 (End stage renal disease)	26,276	1.5755	578,587	2.3010	492,710	3.2761	CC	MCC.
N30.00 (Acute cystitis without hematuria).	18,597	1.0576	53,820	1.9409	73,996	2.8976	Non-CC	CC.
N30.01 (Acute cystitis with hematuria).	4,872	0.9503	16,949	1.8514	24,422	2.8070	Non-CC	CC.
N41.0 (Acute prostatitis)	845	0.9519	3,031	1.8163	2,135	3.0450	Non-CC	CC.
N76.4 (Abscess of vulva)	368	0.8284	1,276	2.0906	1,049	3.1341	Non-CC	CC.

The C1, C2, and C3 values in the table above are generally close to 1.0, 2.0, and 3.0, respectively, which would indicate that these conditions are more aligned with a non-CC than with either a CC or an MCC. However, our clinical advisors believe that patients with a secondary diagnosis of one of the genitourinary conditions in the table above may consume additional resources, including but not limited to monitoring for hypertension, diagnostic tests, and balancing electrolytes. Patients with end-stage renal disease (ICD–10–CM code N18.6) would typically require dialysis in addition to these resources, which our clinical advisors believe is more aligned with an MCC. Therefore, we are proposing to change the severity level designations for the eight codes as shown in the table above.

e. Injury, Poisoning and Certain Other Consequences of External Causes Chapter Codes

In subcategory S32.5 (Fracture of pubis) of the ICD–10–CM diagnosis classification, based on our comprehensive analysis, we are proposing to change the severity level designation from CC to non-CC for 19 ICD–10–CM diagnosis codes that specify fractures of the pubic bone. The following table contains the diagnosis codes for which we are proposing a severity level designation change, and their impact on resource use when reported as a secondary diagnosis.

PROPOSED SEVERITY LEVEL CHANGES, PUBIS FRACTURE CODES AS SECONDARY DIAGNOSIS

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
S32.501A (Unspecified fracture of right pubis, initial encounter for closed fracture).	393	1.0234	1,171	2.1215	847	3.0423	CC	Non-CC.
S32.501K (Unspecified fracture of right pubis, subsequent encounter for fracture with nonunion).	1	1.5125	12	2.1144	2	1.8454	CC	Non-CC.
S32.502A (Unspecified fracture of left pubis, initial encounter for closed fracture).	398	1.3072	1,152	2.0593	914	3.0028	CC	Non-CC.
S32.502K (Unspecified fracture of left pubis, subsequent encounter for fracture with nonunion).	3	0.0000	7	2.8723	1	0.7401	CC	Non-CC.
S32.509A (Unspecified fracture of unspecified pubis, initial encounter for closed fracture).	49	1.1075	156	2.1066	154	3.1704	CC	Non-CC.
S32.509K (Unspecified fracture of unspecified pubis, subsequent encounter for fracture with nonunion).	0	0.0000	1	3.4022	1	2.1306	CC	Non-CC.
S32.511A (Fracture of superior rim of right pubis, initial encounter for closed fracture).	743	1.1812	2,132	2.1519	1,504	2.8763	CC	Non-CC.
S32.511K (Fracture of superior rim of right pubis, subsequent encounter for fracture with nonunion).	2	2.0354	5	0.0000	4	2.3425	CC	Non-CC.

PROPOSED SEVERITY LEVEL CHANGES, PUBIS FRACTURE CODES AS SECONDARY DIAGNOSIS—Continued

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
S32.512A (Fracture of superior rim of left pubis, initial encounter for closed fracture).	760	1.5738	2,098	2.0828	1,590	2.9020	CC	Non-CC.
S32.512K (Fracture of superior rim of left pubis, subsequent encounter for fracture with nonunion).	3	2.1915	3	2.4812	8	4.0000	CC	Non-CC.
S32.519A (Fracture of superior rim of unspecified pubis, initial encounter for closed fracture).	15	2.6829	53	1.5795	35	2.9052	CC	Non-CC.
S32.519K (Fracture of superior rim of unspecified pubis, subsequent encounter for fracture with nonunion).	0	0.000	0	0.000	0	0.000	CC	Non-CC.
S32.591A (Other specified fracture of right pubis, initial encounter for closed fracture).	2,427	1.2524	6,513	2.0970	4,397	2.9930	CC	Non-CC.
S32.591K (Other specified fracture of right pubis, subsequent encounter for fracture with nonunion).	7	2.7706	15	1.9772	5	0.8969	CC	Non-CC.
S32.592A (Other specified fracture of left pubis, initial encounter for closed fracture).	2,424	1.3691	6,604	2.0921	4,922	2.9428	CC	Non-CC.
S32.592K (Other specified fracture of left pubis, subsequent encounter for fracture with nonunion).	4	0.6970	24	2.5574	10	3.0015	CC	Non-CC.
S32.599A (Other specified fracture of unspecified pubis, initial encounter for closed fracture).	151	1.6748	457	2.0518	394	3.1844	CC	Non-CC.
S32.599K (Other specified fracture of unspecified pubis, subsequent encounter for fracture with nonunion).	1	0.0000	0	0.0000	3	1.4709	CC	Non-CC.

The C1, C2, and C3 values in the table above are generally close to 1.0, 2.0, and 3.0, respectively, particularly for those codes for which the highest number of cases were reported. This indicates that these conditions are more aligned with a non-CC than with either a CC or an MCC. Our clinical advisors reviewed these data, particularly with respect to ICD–10–CM diagnosis codes S32.591A and S32.592A which account for the majority of cases in this group, and believe the resources involved in caring for a patient with these conditions are more aligned with a non-CC. Our clinical advisors noted that, similar to the proposed severity level designation changes in the Neoplasms chapter of the ICD–10–CM diagnosis classification discussed above, if patients are admitted for treatment of an acute or nonunion fracture of the pubic bone, the fracture is the principal diagnosis, and other complicating or comorbid conditions reported as secondary diagnoses would determine the appropriate severity level for each particular case. For example, if a patient is admitted for surgical treatment of the nonunion of a right pubic fracture at the superior rim, ICD–10–CM diagnosis code S32.511K (Fracture of superior rim of right pubis, subsequent encounter for fracture with nonunion) is reported as the principal diagnosis. Because our clinical advisors believe that it is appropriate to ensure consistency across codes involving similar diagnoses, we are proposing to reassign the severity level for all of the codes in the table above from a CC to a non-CC.

In category S72 (Fracture of femur) of the ICD–10–CM classification, based on our comprehensive analysis, we are proposing to change the severity level designation from MCC to CC for 35 ICD–10–CM diagnosis codes specifying fractures of the hip. The following table contains the Injury, Poisoning and Certain Other Consequences of External Causes chapter codes for which we are proposing a severity level change, and their impact on resource use when reported as a secondary diagnosis.

PROPOSED SEVERITY LEVEL CHANGES, HIP FRACTURE CODES AS SECONDARY DIAGNOSIS

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
S72.011A (Unspecified intracapsular fracture of right femur, initial encounter for closed fracture).	145	2.1400	464	2.3419	700	2.9623	MCC	CC.
S72.012A (Unspecified intracapsular fracture of left femur, initial encounter for closed fracture).	155	2.0099	455	2.2738	754	3.0423	MCC	CC.

PROPOSED SEVERITY LEVEL CHANGES, HIP FRACTURE CODES AS SECONDARY DIAGNOSIS—Continued

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
S72.019A (Unspecified intracapsular fracture of unspecified femur, initial encounter for closed fracture).	1	0.9364	4	1.0008	10	2.7267	MCC	CC.
S72.111A (Displaced fracture of greater trochanter of right femur, initial encounter for closed fracture).	266	1.5110	605	2.2983	442	3.1874	MCC	CC.
S72.112A (Displaced fracture of greater trochanter of left femur, initial encounter for closed fracture).	249	1.7779	573	2.4626	418	3.0108	MCC	CC.
S72.113A (Displaced fracture of greater trochanter of unspecified femur, initial encounter for closed fracture).	11	1.7739	21	2.9650	23	3.5762	MCC	CC.
S72.114A (Nondisplaced fracture of greater trochanter of right femur, initial encounter for closed fracture).	112	0.8826	339	2.1640	178	3.1028	MCC	CC.
S72.115A (Nondisplaced fracture of greater trochanter of left femur, initial encounter for closed fracture).	118	1.3960	288	2.0607	202	2.8640	MCC	CC.
S72.116A (Nondisplaced fracture of greater trochanter of unspecified femur, initial encounter for closed fracture).	3	0.9472	8	1.3030	3	3.4270	MCC	CC.
S72.121A (Displaced fracture of lesser trochanter of right femur, initial encounter for closed fracture).	22	2.0288	74	3.1110	49	3.1174	MCC	CC.
S72.122A (Displaced fracture of lesser trochanter of left femur, initial encounter for closed fracture).	23	1.1648	75	2.9379	40	2.4430	MCC	CC.
S72.123A (Displaced fracture of lesser trochanter of unspecified femur, initial encounter for closed fracture).	0	0.0000	2	0.0000	6	2.2881	MCC	CC.
S72.124A (Nondisplaced fracture of lesser trochanter of right femur, initial encounter for closed fracture).	4	0.9792	19	2.4244	8	2.7792	MCC	CC.
S72.125A (Nondisplaced fracture of lesser trochanter of left femur, initial encounter for closed fracture).	5	0.6759	13	1.2700	7	3.1292	MCC	CC.
S72.126A (Nondisplaced fracture of lesser trochanter of unspecified femur, initial encounter for closed fracture).	0	0.0000	0	0.0000	1	1.1159	MCC	CC.
S72.131A (Displaced apophyseal fracture of right femur, initial encounter for closed fracture).	1	3.4327	0	0.0000	2	4.0000	MCC	CC.
S72.132A (Displaced apophyseal fracture of left femur, initial encounter for closed fracture).	0	0.0000	1	2.6423	0	0.0000	MCC	CC.
S72.134A (Nondisplaced apophyseal fracture of right femur, initial encounter for closed fracture).	0	0.000	1	3.501	0	0.000	MCC	CC.
S72.135A (Nondisplaced apophyseal fracture of left femur, initial encounter for closed fracture).	0	0.000	0	0.000	0	0.000	MCC	CC.
S72.136A (Nondisplaced apophyseal fracture of unspecified femur, initial encounter for closed fracture).	0	0.000	0	0.000	0	0.000	MCC	CC.

PROPOSED SEVERITY LEVEL CHANGES, HIP FRACTURE CODES AS SECONDARY DIAGNOSIS—Continued

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
S72.141A (Displaced intertrochanteric fracture of right femur, initial encounter for closed fracture).	289	2.2607	894	2.6329	1,293	3.1692	MCC	CC.
S72.142A (Displaced intertrochanteric fracture of left femur, initial encounter for closed fracture).	347	2.2587	972	2.5641	1,405	3.1003	MCC	CC.
S72.143A (Displaced intertrochanteric fracture of unspecified femur, initial encounter for closed fracture).	10	2.3446	21	1.0169	35	3.3080	MCC	CC.
S72.144A (Nondisplaced intertrochanteric fracture of right femur, initial encounter for closed fracture).	44	1.7331	149	2.4637	168	3.1302	MCC	CC.
S72.145A (Nondisplaced intertrochanteric fracture of left femur, initial encounter for closed fracture).	39	1.9170	112	2.8435	170	3.2612	MCC	CC.
S72.146A (Nondisplaced intertrochanteric fracture of unspecified femur, initial encounter for closed fracture).	0	0.0000	9	1.2250	2	0.0000	MCC	CC.
S72.21XA (Displaced subtrochanteric fracture of right femur, initial encounter for closed fracture).	57	1.7697	159	2.2460	205	3.1614	MCC	CC.
S72.22XA (Displaced subtrochanteric fracture of left femur, initial encounter for closed fracture).	70	2.3685	160	2.6079	184	3.2178	MCC	CC.
S72.23XA (Displaced subtrochanteric fracture of unspecified femur, initial encounter for closed fracture).	0	0.0000	9	3.4708	6	3.3401	MCC	CC.
S72.24XA (Nondisplaced subtrochanteric fracture of right femur, initial encounter for closed fracture).	12	0.5442	22	2.7275	11	3.6028	MCC	CC.
S72.25XA (Nondisplaced subtrochanteric fracture of left femur, initial encounter for closed fracture).	13	1.7115	25	2.1005	17	3.1686	MCC	CC.
S72.26XA (Nondisplaced subtrochanteric fracture of unspecified femur, initial encounter for closed fracture).	0	0.0000	1	2.0474	0	0.0000	MCC	CC.
S72.301A (Unspecified fracture of shaft of right femur, initial encounter for closed fracture).	61	2.3462	156	3.0491	159	3.5567	MCC	CC.
S72.302A (Unspecified fracture of shaft of left femur, initial encounter for closed fracture).	71	2.6314	186	2.4838	157	3.4436	MCC	CC.

As shown in the table above, all of these secondary diagnoses are currently designated as MCCs. The C2 values of the codes most frequently reported, ICD–10–CM codes S72.142A and S72.141A, are closer to 3.0 than 2.0, which indicates that they are more clinically aligned with a CC than an MCC. Therefore, the data suggest that when fracture of the hip codes are reported as a secondary diagnosis, the resources involved in caring for patients with these conditions are more aligned with a CC than an MCC. Our clinical advisors reviewed these data and believe the resources involved in caring for patients with these conditions are more aligned with a CC. While we note that there is little to no data for some of these ICD–10–CM codes as secondary diagnoses, there is sufficient data for clinically similar secondary diagnoses. Therefore, because our clinical advisors believe that it is appropriate to ensure consistency across codes involving similar diagnoses, we are proposing to reassign the severity level for all of the codes in the table above from an MCC to a CC.

(f) Factors Influencing Health Status and Contact With Health Services

The last chapter of the ICD–10–CM classification specifies other factors that influence a patient's health status or necessitate contact with health care

providers (Z00–Z99). Of these ICD–10–CM codes, based on our comprehensive review, we are proposing to change the severity level designation from non-CC to CC for four codes specifying anti-microbial drug resistance and one code specifying homelessness. Based on this same review, we also are proposing to change the severity level designation from CC to non-CC for 3 ICD–10–CM codes specifying adult body mass index (BMI) ranges and 13 ICD–10–CM codes indicating that the patient has previously undergone an organ transplant or cardiac device implantation with no current complications (the code indicates status only).

The following table contains the five codes for which we are proposing a severity level change from non-CC to CC and their impact on resource use when reported as a secondary diagnosis.

PROPOSED SEVERITY LEVEL CHANGES FOR Z CHAPTER CODES AS SECONDARY DIAGNOSIS

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
Z16.12 (Extended spectrum beta lactamase (ESBL) resistance).	3,082	2.1134	19,692	2.5995	25,544	3.1752	Non-CC	CC.
Z16.21 (Resistance to vancomycin)	692	2.1507	6,733	2.8659	11,672	3.3365	Non-CC	CC.
Z16.24 (Resistance to multiple antibiotics).	2,970	1.5821	16,097	2.4086	20,738	3.1174	Non-CC	CC.
Z16.39 (Resistance to other specified antimicrobial drug).	448	1.2003	2,326	2.2555	2,494	3.1127	Non-CC	CC.
Z59.0 (Homelessness)	14,927	1.5964	41,328	2.3012	22,101	3.1256	Non-CC	CC.

As indicated above, a value close to 2.0 in column C1 suggests that the secondary diagnosis is more aligned with a CC than a non-CC. Because the C1 values in the table above are generally close to 2, the data suggest that when these five Z chapter diagnosis codes are reported as a secondary diagnosis, the resources involved in caring for a patient with other factors such as homelessness support increasing the severity level from a non-CC to a CC. Our clinical advisors reviewed these data and believe the resources involved in caring for patients with these other reported factors are more aligned with a CC.

While we note that ICD–10–CM diagnosis code Z16.39 does not follow this pattern, our clinical advisors believe that this code is clinically similar to the other diagnoses in the table above describing anti-microbial drug resistance. Therefore, because our clinical advisors believe that it is appropriate to ensure consistency across codes involving similar diagnoses, we are proposing to reassign the severity level for all four of the codes specifying anti-microbial drug resistance in the table above from a non-CC to a CC.

The following table contains the 14 BMI and transplant/cardiac device status codes for which we are proposing a severity level designation change from CC to non-CC, and their impact on resource use when reported as a secondary diagnosis.

PROPOSED SEVERITY LEVEL CHANGES FOR Z CHAPTER BMI AND TRANSPLANT/CARDIAC DEVICE STATUS CODES AS SECONDARY DIAGNOSIS

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
Z68.1 (Body mass index (BMI) 19.9 or less, adult).	18,983	1.1170	244,156	2.2082	350,731	3.0733	CC	Non-CC.
Z68.41 (Body mass index (BMI) 40.0–44.9, adult).	139,420	1.1139	209,300	2.0752	213,929	3.0814	CC	Non-CC.
Z68.42 (Body mass index (BMI) 45.0–49.9, adult).	60,408	1.1643	102,897	2.0783	109,928	3.0867	CC	Non-CC.
Z94.0 (Kidney transplant status)	18,649	1.0277	70,484	2.0573	45,382	3.1032	CC	Non-CC.
Z94.1 (Heart transplant status)	2,311	1.0649	8,138	2.2471	5,037	3.2653	CC	Non-CC.
Z94.2 (Lung transplant status)	1,461	1.0886	5,032	2.1898	3,466	3.1285	CC	Non-CC.
Z94.3 (Heart and lungs transplant status).	20	0.8287	88	3.0647	59	3.1675	CC	Non-CC.
Z94.4 (Liver transplant status)	6,050	0.9811	17,556	2.0323	12,970	3.1688	CC	Non-CC.
Z94.81 (Bone marrow transplant status).	1,655	0.9778	5,447	2.0919	5,150	3.1918	CC	Non-CC.
Z94.82 (Intestine transplant status)	119	1.5661	351	2.1844	230	3.2081	CC	Non-CC.
Z94.83 (Pancreas transplant status)	1,789	1.2032	7,788	2.0739	4,536	3.1381	CC	Non-CC.
Z94.84 (Stem cells transplant status).	3,083	1.1451	10,412	2.3041	8,835	3.2932	CC	Non-CC.
Z95.811 (Presence of heart assist device).	1,053	1.6453	7,373	2.3089	5,974	3.1198	CC	Non-CC.
Z95.812 (Presence of fully implantable artificial heart).	45	2.0467	132	2.5603	142	2.4139	CC	Non-CC.

The C1, C2, and C3 values in the table above are generally close to 1.0, 2.0, and 3.0, respectively. This indicates that these conditions are more aligned with a non-CC than with either a CC or an MCC. Therefore, the data suggest that when these BMI and transplant/cardiac device status codes are reported as a secondary diagnosis, the resources involved in caring for patients with these conditions indicating health status are not aligned with those of a CC. Our clinical advisors reviewed these data and believe the resources involved in caring for patients with these conditions indicating health status are more aligned with a non-CC. Our clinical advisors noted that, in the absence of a diagnosis that represents a complication of the patient's current status, the presence of a BMI within a stated range or the fact that a patient has previously undergone a transplant or cardiac device implant is not by itself a clinical indication of increased severity of illness. Therefore, we are proposing to reassign the severity level for all of the codes in the table above from a CC to a non-CC.

(3) Results of Impact Analysis

Using claims data from the September 2018 update of the FY 2018 MedPAR file, we employed the following method to determine the impact of changing severity level designation for the 1,492 ICD–10–CM diagnosis codes. Edits and cost estimations used for relative weight calculations were applied, resulting in 8,908,404 IPPS claims analyzed for this impact evaluation of our proposed changes to severity levels. We refer readers to section II.G. of the preamble of this proposed rule for further information regarding the methodology for calculation of the proposed relative weights.

First, we analyzed the 8,908,404 IPPS claims using the Version 36 ICD–10 MS–DRG GROUPER to determine the current distribution of severity level designation. We identified 3,648,331 cases (41.0 percent) reporting one or more secondary diagnosis codes assigned to the MCC severity level, 3,612,600 cases (40.5 percent) reporting one or more secondary diagnosis codes assigned to the CC severity level, and 1,647,473 cases (18.5 percent) not reporting a secondary diagnosis code assigned to the MCC or CC severity level.

Next, we reprocessed the 8,908,404 claims using the proposed change in severity level designation for the 1,492 ICD–10–CM diagnosis codes to determine the impact on the distribution of severity level designation. We identified 3,236,493 cases (36.3 percent) reporting one or more secondary diagnosis codes that would be assigned to the MCC severity level, 3,589,677 cases (40.3 percent) reporting one or more secondary diagnosis codes that would be assigned to the CC severity level, and 2,082,234 cases (23.4 percent) not reporting a secondary diagnosis code that would be assigned to the MCC or CC severity level.

Below we provide a summary of the steps followed for the analysis performed.

Step 1.—Analyzed 8,908,404 claims to determine the current distribution of severity level designation.

SEVERITY LEVEL DISTRIBUTION BEFORE PROPOSED CHANGES—8,908,404 CLAIMS ANALYZED

Number of cases reporting one or more secondary diagnosis codes assigned to the MCC severity level	3,648,331 (41.0%)
Number of cases reporting one or more secondary diagnosis codes assigned to the CC severity level	3,612,600 (40.5%)
Number of cases reporting no secondary diagnosis codes assigned to the MCC or CC severity level	1,647,473 (18.5%)

Step 2.—Made proposed severity level changes to 1,492 ICD–10–CM codes.

STEP 2—MADE PROPOSED SEVERITY LEVEL CHANGES TO 1,492 ICD–10–CM CODES.

Current version 36 severity level	Proposed version 37 severity level	Number of codes
Non-CC	CC	183
CC	Non-CC	1,148
CC	MCC	8
MCC	Non-CC	17
MCC	CC	136
Total		1,492

Step 3.—Reprocessed 8,908,404 claims to determine severity level distribution after changes.

SEVERITY LEVEL DISTRIBUTION AFTER PROPOSED CHANGES—8,908,404 CLAIMS ANALYZED

Number of cases reporting one or more secondary diagnosis codes assigned to the MCC severity level	3,236,493 (36.3%)
Number of cases reporting one or more secondary diagnosis codes assigned to the CC severity level	3,589,677 (40.3%)
Number of cases reporting no secondary diagnosis codes assigned to the MCC or CC severity level	2,082,234 (23.4%)

The overall statistics by CC subgroup for the proposed Version 37 MS–DRGs are contained in the table below. Cases in the MCC subgroup have average costs that are 62 percent higher than the average costs for cases in the CC subgroup. The CC subgroup with the largest number of cases is the CC subgroup with 40.3 percent of the cases.

OVERALL STATISTICS FOR PROPOSED MS–DRGS

CC subgroup	Number of cases	Percent	Average costs
Major	3,236,493	36.3	$16,890
CC	3,589,677	40.3	10,518
Non-CC	2,082,234	23.4	10,166

The distribution of cases across the different types of CC subgroups in the proposed Version 37 MS–DRGs is contained in the table below. The table shows that 91 percent of the cases would be assigned to base MS–DRGs with three CC subgroups, and only 9 percent of the cases would be assigned to base MS–DRGs with no CC subgroups.

DISTRIBUTION OF PATIENT BY TYPE OF CC SUBGROUP IN PROPOSED VERSION 37 MS–DRGS

CC subgroup	Number	Percent
None	68	9
(MCC and CC), Non-CC	84	11
MCC, (CC and Non-CC)	132	17
MCC, CC, and Non-CC	477	63
Total	761	

We performed regression analysis to compare the variance in the MS–DRGs with and without the proposed severity level designation changes and thereby the impact of payment to cost ratios. The results of the regression analysis showed a slight decrease in variance with the proposed severity level designation changes, showing an R-squared of 35.9 percent after making the severity level changes, compared with an R-squared of 35.6 percent in the current Version 36 ICD–10 MS–DRG GROUPER. This indicates that the proposed severity level changes increase the explanatory power of the GROUPER in capturing differences in expected cost between the MS–DRGs and thus would improve the overall accuracy of the IPPS payment system.

After considering the results of our data analysis, the clinical judgment of our clinical advisors, and the overall aggregate impact of these changes, we are proposing a change to the severity level designations for 1,492 ICD–10–CM diagnosis codes as shown in Table 6P.1c. associated with this proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.)

d. Requested Changes to Severity Levels

(1) Acute Right Heart Failure

We received a request to change the severity level for ICD–10–CM diagnosis codes I50.811 (Acute right heart failure) and I50.813 (Acute on chronic right heart failure) from a non-CC to an MCC. The requestor stated that similar diagnosis codes in the classification are designated as an MCC. We used the approach outlined earlier in this section to evaluate this request. The following table shows the claims data that were used to evaluate this request:

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Requested CC subclass
I50.811 Acute right heart failure	92	1.3290	470	2.5375	1,632	3.1907	non-CC	MCC.
I50.813 Acute on chronic right heart failure.	183	1.4412	1,189	2.6036	3,099	3.2870	non-CC	MCC.

For ICD–10–CM diagnosis code I50.811, the data suggest that the resources involved in caring for a patient with this condition are 33 percent greater than expected when the patient has either no other secondary diagnosis present, or all the other secondary diagnoses present are non-CCs. The resources are 54 percent greater than expected when reported in conjunction with another secondary diagnosis that is a CC, and 19 percent greater than expected when reported in conjunction with another secondary diagnosis code that is an MCC. Our clinical advisors reviewed this request and agree that the resources involved in caring for a patient with this condition are not aligned with those of an MCC.

For ICD–10–CM diagnosis code I50.813, the data suggest that the resources involved in caring for a patient with this condition are 44 percent greater than expected when the patient has either no other secondary diagnosis present or all the other secondary diagnoses present are non-CCs. The resources are 60 percent greater than expected when reported in conjunction with another secondary diagnosis that is a CC, and 28 percent greater than expected when reported in conjunction with another secondary diagnosis code that is an MCC. Our clinical advisors reviewed this request and agree that the resources involved in caring for a patient with this condition are not aligned with those of an MCC.

However, we note that although the data suggest that the resources involved in caring for a patient with this condition are not aligned with those of an MCC, the data suggest and our clinical advisors believe that the resources appear to be aligned with

those of a CC. Therefore, we are soliciting public comment on whether a CC severity level designation for ICD–10–CM diagnosis codes I50.811 and I50.813 for FY 2020 is appropriate.

(2) Chronic Right Heart Failure

We received a request to change the severity level for ICD–10–CM diagnosis code I50.812 (Chronic right heart failure) from a non-CC to a CC. The requestor stated that this code warrants CC classification because it indicates the presence and treatment of chronic heart failure. We used the approach outlined earlier to evaluate this request. The following table contains the data that we used to evaluate this request:

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Requested CC subclass
I50.812 Chronic right heart failure ..	179	1.5114	1,533	2.1146	1,758	3.0549	non-CC	CC.

For ICD–10–CM diagnosis code I50.812, the data suggest that the resources involved in caring for a patient with this condition are 51 percent greater than expected when the patient has either no other secondary diagnosis present or all the other secondary diagnoses present are non-CCs. The resources are 11 percent greater than expected when reported in conjunction with another secondary diagnosis that is a CC, and 5 percent greater than expected when reported in conjunction with another secondary diagnosis code that is an MCC. Our clinical advisors reviewed this request and agree that the resources involved in caring for a patient with this condition are not aligned with those of a CC. Therefore, we are not proposing a change to the severity level for ICD–10–CM diagnosis code I50.812.

(3) Ascites in Alcoholic Liver Disease and Toxic Liver Disease

We received a request to change the severity level for ICD–10–CM diagnosis codes K70.11 (Alcoholic hepatitis with ascites), K70.31 (Alcoholic cirrhosis with ascites), and K71.51 (Toxic liver disease with chronic active hepatitis with ascites) from a non-CC to a CC. The requestor stated that these codes warrant CC classification because providers are not currently compensated for the ascites treatment. We used the approach outlined earlier to evaluate this request. The following table contains the data that we used to evaluate this request.

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Requested CC subclass
K70.11 Alcoholic hepatitis with ascites.	134	1.2952	1,940	2.3444	3,331	3.3635	non-CC	CC.
K70.31 Alcoholic cirrhosis with ascites.	1,634	1.1129	18,675	2.2301	26,822	3.2479	non-CC	CC.
K71.51 Toxic liver disease with chronic active hepatitis with ascites.	16	0.8913	218	2.1743	274	3.1418	non-CC	CC.

For ICD–10–CM diagnosis code K70.11, the data suggest that the resources involved in caring for a patient with this condition are 29 percent greater than expected when the patient has either no other secondary diagnosis present or all the other secondary diagnoses present are non-CCs. The resources are 34 percent greater than expected when reported in conjunction with another secondary diagnosis that is a CC, and 36 percent greater than expected when reported in conjunction with another secondary diagnosis code that is an MCC. Our clinical advisors reviewed this request and agree that the resources involved in caring for a patient with this condition are not aligned with those of a CC. Therefore, we are not proposing a change to the severity level for ICD–10–CM diagnosis code K70.11.

For ICD–10–CM diagnosis code K70.31, the data suggest that the resources involved in caring for a patient with this condition are 11 percent greater than expected when the patient has either no other secondary diagnosis present or all the other secondary diagnoses present are non-CCs. The resources are 23 percent greater than expected when reported in conjunction with another secondary diagnosis that is a CC, and 25 percent greater than expected when reported in conjunction with another secondary diagnosis code that is an MCC. Our clinical advisors reviewed this request and agree that the resources involved in caring for a patient with this condition are not aligned with those of a CC. Therefore, we are not proposing a change to the severity level for ICD–10–CM diagnosis code K70.31.

For ICD–10–CM diagnosis code K71.51, the data suggest that the resources involved in caring for a patient with this condition are 11 percent lower than expected when the patient has either no other secondary diagnosis present, or all the other secondary diagnoses present are non-CCs. The resources are 17 percent greater than expected when reported in conjunction with another secondary diagnosis that is a CC, and 14 percent greater than expected when reported in conjunction with another secondary diagnosis code that is an MCC. Our clinical advisors reviewed this request and agree that the resources involved in caring for a patient with this condition are not aligned with those of a CC. Therefore, we are not proposing a change to the severity level for ICD–10–CM diagnosis code K71.51.

(4) Factitious Disorder Imposed on Self

We received a request to change the severity level for ICD–10–CM diagnosis codes F68.11 (Factitious disorder imposed on self, with predominantly psychological signs and symptoms) and F68.13 (Factitious disorder imposed on self, with combined psychological and physical signs and symptoms) from a

non-CC to a CC. The requestor stated that similar codes in the classification are designated as a CC. We used the approach outlined earlier to evaluate this request. The following table contains the data that we used to evaluate this request.

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Requested CC subclass
F68.11 Factitious disorder imposed on self, with predominantly psychological signs and symptoms.	16	1.2040	59	0.9979	15	3.2395	non-CC	CC.
F68.13 Factitious disorder imposed on self, with combined psychological and physical signs and symptoms.	4	1.6226	32	1.9840	11	4.0000	non-CC	CC.

For ICD–10–CM diagnosis code F68.11, the number of patients found in the September 2018 update of the FY 2018 MedPAR data in each of the subsets is 16, 59, and 15, and for ICD–10–CM diagnosis code F68.13, the number of patients in each of the subsets is 4, 32, and 11. Our clinical advisors reviewed this request and believe that due to the small number of cases in the data, it is not possible to use statistical methods to evaluate the impact on resource use of patients. Our clinical advisors also do not believe there is a clinical basis to change the severity level in the absence of data. Our clinical advisors noted that if a patient was diagnosed with either one of these ICD–10–CM diagnoses (ICM–10–CM diagnosis code F68.11 or F68.13), there would more than likely be another diagnosis code reported that identifies the psychological and/or physical symptoms the patient is experiencing that may be a better indicator of resources utilized because these patients often fabricate their illness and inflict injuries on themselves to receive attention. For example, a patient may cut his or her finger, resulting in a wound which requires repair. It is the cut and need for repair that contribute to the resources consumed in caring for a patient with this diagnosis. Therefore, we are not proposing a change to the severity level for ICD–10–CM diagnosis codes F68.11 and F68.13 at this time.

(5) Nonunion and Malunion of Physeal Metatarsal Fractures

We received a request to change the severity level designations for the following six ICD–10–CM diagnosis codes from a non-CC to a CC: S99.101B (Unspecified physeal fracture of right metatarsal, initial encounter for open fracture); S99.101K (Unspecified physeal fracture of right metatarsal, subsequent encounter for fracture); S99.101P (Unspecified physeal fracture of right metatarsal, subsequent encounter for fracture with malunion); S99.132B (Salter-Harris Type III physeal fracture of left metatarsal, initial encounter for open fracture), S99.132K (Salter-Harris Type III physeal fracture of left metatarsal, subsequent encounter for fracture with nonunion); and S99.132P (Salter-Harris Type III physeal fracture of left metatarsal, subsequent encounter for fracture with malunion with nonunion). The requestor stated that similar codes for open fractures, nonunions, and malunions of other sites currently are designated as CCs. However the requestor did not provide the specific ICD–10–CM diagnosis codes that are currently designated as CCs that the requestor believes are an appropriate comparator. There are a considerable number of fractures, nonunions, and malunions of other sites, some of which are designated as CCs and others that are not. In particular, in evaluating this request, we would want to review the appropriateness of designating unspecified codes (that is, ICD–10–CM diagnosis codes S99.101B, S99.101K, and S99.101P) as a CC, to avoid potentially discouraging more detailed coding. In addition, none of the other ICD–10–CM diagnosis codes describing Salter-Harris fractures (for example, ICD–10–CM diagnosis codes in sub-subcategory S99.11– (Salter-Harris Type I physeal fracture of metatarsal), S99.12– (Salter-Harris Type II physeal fracture of metatarsal), S99.13– (Salter-Harris Type III physeal fracture of metatarsal), and S99.14– (Salter-Harris Type IV physeal fracture of metatarsal)) currently have a CC designation.

Given the lack of supporting information for this request and because we believe this request may require further research and analysis to evaluate the relevant category of fracture codes and fully assess the claims data, we are unable to fully evaluate this request for FY 2020. Therefore, at this time, we are not proposing changes to the severity level designations for ICD–10–CM diagnosis codes S99.101B, S99.101K, S99.101P, S99.132B, S99.132K, and S99.132P as the requestor recommended.

(6) Other Encephalopathy

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20241), we discussed a request that we had received to change the severity level designation for ICD–10–CM diagnosis code G93.40 (Encephalopathy, unspecified) from an MCC to a non-CC. We did not propose a change based on the review of the claims data and input from our clinical advisors. However, after a review of public comments in response to that proposal, we finalized a change in the severity level designation for ICD–10–CM diagnosis code G93.40 from an MCC to a CC (83 FR 41239).

We received a request to reconsider the change in the severity level designation for ICD–10–CM diagnosis code G93.49 (Other encephalopathy) from an MCC to a CC, as reflected in Table 6I.2—Deletions to the MCC List and Table 6J.—Complete CC List that were associated with the FY 2019 IPPS/LTCH PPS final rule, because the requestor noted this diagnosis code was not discussed in the FY 2019 IPPS/LTCH PPS proposed or final rules along with the discussion of related ICD–10–CM diagnosis code G93.40. The requestor stated that diagnosis code G93.49 warrants an MCC classification to accurately reflect severity of illness and resources contributing to an extended length of stay for patients who have this condition.

Our clinical advisors reviewed the data for ICD–10–CM diagnosis code G93.49 (Other encephalopathy) as set forth in the table below, and noted that the C1 value is close to 2.0, which indicates that the resource use is aligned with that of a CC, while the C2 value is about halfway between 2.0 and 3.0, which is also consistent with the resource use of a CC. They also compared the C1, C2, and C3 values of diagnosis code G93.49 to those of diagnosis code G93.40, as also set forth in the table below, and noted that the values were similar for both codes. Our clinical advisors noted that similar to diagnosis code G93.40, diagnosis code

G93.49 (Other encephalopathy) is poorly defined, not all encephalopathies are MCCs, and the MCC status may create an incentive for coding personnel to not pursue specificity of encephalopathy. Therefore, they believe that these conditions are clinically similar and should be assigned the same CC severity level status. Therefore, we are not proposing any change to the severity level for ICD 10 CM diagnosis code G93.49 (Other encephalopathy) for FY 2020.

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3
G93.40 (Encephalopathy, unspecified)	32,023	1.812	161,991	2.494	294,088	3.289
G93.49 (Other encephalopathy)	4,258	1.758	23,203	2.536	40,836	3.349

(7) Obstetrics Chapter Codes

We received a request to change the severity level for 94 ICD–10–CM diagnosis codes in the Obstetrics chapter of the ICD–10–CM diagnosis classification that describe a variety of complications of pregnancy, childbirth and the puerperium. The requestor stated that the reclassification of the 94 obstetric diagnosis codes would more appropriately reflect severity of illness and accurate MS–DRG grouping after CMS' FY 2019 creation of new obstetric MS–DRGs subdivided by severity level (with MCC, with CC, and without CC/MCC).

The 94 obstetrics codes associated with this request and their current and requested severity level designation are shown in Table 6P.1e. associated with this proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). We are proposing to move some of these diagnosis codes to a higher severity level and some diagnosis codes to a lower severity level. Our proposals are shown in the table below.

Our clinical advisors indicated that the approach outlined elsewhere in this section to evaluate requested changes to severity levels, in which each diagnosis is evaluated using Medicare cost data to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use, could not be used to evaluate this request because the number of obstetric patients in the Medicare data was insufficient to perform evaluation using statistical methods. Instead, our clinical advisors used their clinical judgment to evaluate the requested changes to the severity levels for the 94 obstetrics diagnosis codes. Our clinical advisors concur with the requestor that changes to the severity level for some of the obstetrics diagnosis codes would more appropriately reflect severity of illness and accurate MS–DRG grouping. Specifically, our clinical advisors agreed with the requested change to severity from a non-CC to a CC for 10 of the diagnosis codes identified by the requestor because they believe these conditions clinically warrant a CC designation. They noted that 6 of the 10 diagnosis codes describe gestational diabetes mellitus in pregnancy, gestational diabetes mellitus in childbirth, or gestational diabetes mellitus in the puerperium requiring control, either by insulin or oral hypoglycemic drugs and the condition would require additional monitoring and resources in the inpatient setting. They also noted that 2 of the 10 diagnosis codes describe maternal care for other isoimmunization in the first trimester for single or multiple gestations where the fetus is unspecified or fetus number 1 is specified. They indicated that although there are additional diagnosis codes describing maternal care for other isoimmunization in the first trimester that uniquely identify fetus number 2 through fetus number 5, as well as an ''other'' fetus beyond number 5, they do not believe these other diagnosis codes have any additional impact on resource use because treatment would be directed at the entire uterine cavity. They further noted that 1 of the 10 diagnosis codes describes a conjoined twin pregnancy in the third trimester and, while conjoined twins occur rarely and carry a high risk of complications and mortality, they believe the complexities are greatest in the third trimester. Lastly, 1 of the 10 diagnosis codes describes unspecified diabetes mellitus in childbirth, and because the diagnosis codes describing unspecified diabetes mellitus in pregnancy and unspecified diabetes mellitus in the puerperium are designated as a CC, our clinical advisors agreed that clinically, the condition occurring in childbirth warrants a CC designation as well. Our clinical advisors also agreed with the requested change to severity level from an MCC to a CC for 4 other diagnosis codes identified by the requestor because, clinically, the CC designation is consistent with the other diagnosis codes within those diagnosis code families. For example, the diagnosis codes describing preexisting type 1 diabetes mellitus in pregnancy, preexisting type 2 diabetes mellitus in pregnancy and unspecified preexisting diabetes mellitus in pregnancy, regardless of trimester (first, second, third, and unspecified) are all designated as CCs. Our clinical advisors agreed that the diagnosis codes describing these same conditions ''in childbirth'' also warrant a CC designation because the conditions do not require additional resources or reflect a greater severity of illness compared to the conditions when they occur ''in pregnancy''. Therefore, we are proposing a change to the severity level for 14 ICD–10–CM diagnosis codes as shown in the following table.

ICD–10–CM diagnosis code	Current CC subclass	Proposed CC subclass
O24.02 (Pre-existing type 1 diabetes mellitus, in childbirth)	MCC	CC.
O24.12 (Pre-existing type 2 diabetes mellitus, in childbirth)	MCC	CC.
O24.32 (Unspecified pre-existing diabetes mellitus in childbirth)	MCC	CC.
O24.414 (Gestational diabetes mellitus in pregnancy, insulin controlled)	Non-CC	CC.
O24.415 (Gestational diabetes mellitus in pregnancy, controlled by oral hypoglycemic drugs)	Non-CC	CC.
O24.424 (Gestational diabetes mellitus in childbirth, insulin controlled)	Non-CC	CC.
O24.425 (Gestational diabetes mellitus in childbirth, controlled by oral hypoglycemic drugs)	Non-CC	CC.
O24.434 (Gestational diabetes mellitus in the puerperium, insulin controlled)	Non-CC	CC.
O24.435 (Gestational diabetes mellitus in puerperium, controlled by oral hypoglycemic drugs)	Non-CC	CC.
O24.82 (Other pre-existing diabetes mellitus in childbirth)	MCC	CC.
O24.92 (Unspecified diabetes mellitus in childbirth)	Non-CC	CC.

ICD–10–CM diagnosis code	Current CC subclass	Proposed CC subclass
O30.023 (Conjoined twin pregnancy, third trimester)	Non-CC	CC.
O36.1910 (Maternal care for other isoimmunization, first trimester, not applicable or unspecified)	Non-CC	CC.
O36.1911 (Maternal care for other isoimmunization, first trimester, fetus 1)	Non-CC	CC.

Given the limited number of cases reporting ICD–10–CM obstetrical codes in the Medicare claims data, we note that use of datasets other than MedPAR cost data for future evaluation of severity level designation for the ICD–10–CM diagnosis codes from the Obstetrics chapter of the ICD–10–CM classification is under consideration.

e. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2020

The following tables identify the proposed additions and deletions to the diagnosis code MCC severity levels list and the proposed additions and deletions to the diagnosis code CC severity levels list for FY 2020 and are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Table 6I.1—Proposed Additions to the MCC List—FY 2020;

Table 6I.2—Proposed Deletions to the MCC List—FY 2020;

Table 6J.1—Proposed Additions to the CC List—FY 2020; and

Table 6J.2—Proposed Deletions to the CC List—FY 2020.

f. Proposed CC Exclusions List for FY 2020

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

In this FY 2020 IPPS/LTCH PPS proposed rule, for FY 2020, we are proposing changes to the ICD–10 MS–DRGs Version 37 CC Exclusion List. Therefore, we have developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2020; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2020; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2020; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2020. For Table 6G.1, each secondary diagnosis code proposed for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses proposed to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions proposed for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code proposed for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the proposed deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Tables 6G.1., 6G.2., 6H.1., and 6H.2. associated with this proposed rule are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

15. Proposed Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

To identify new, revised and deleted diagnosis and procedure codes, for FY 2020, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for this proposed rule.

These tables are not published in the Addendum to this proposed rule but are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this proposed rule. As discussed in section II.F.18. of the preamble of this proposed rule, the code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

We are proposing the MDC and MS–DRG assignments for the new diagnosis and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. In addition, the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. and the proposed O.R. status for the new procedure codes are set forth in Table 6B.

We are making available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*

the following tables associated with this proposed rule:

- Table 6A.—New Diagnosis Codes—FY 2020;
- Table 6B.—New Procedure Codes—FY 2020;
- Table 6C.—Invalid Diagnosis Codes—FY 2020;
- Table 6D.—Invalid Procedure Codes—FY 2020;
- Table 6E.—Revised Diagnosis Code Titles—FY 2020;
- Table 6F.—Revised Procedure Code Titles—FY 2020;
- Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2020;
- Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2020;
- Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2020;
- Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2020;
- Table 6I.1.—Proposed Additions to the MCC List—FY 2020;
- Table 6I.2.–Proposed Deletions to the MCC List—FY 2020;
- Table 6J.1.—Proposed Additions to the CC List—FY 2020; and
- Table 6J.2.—Proposed Deletions to the CC List—FY 2020.

16. Proposed Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41220), we made available the FY 2019 ICD–10 MCE Version 36 manual file. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 36 (and ICD–10 MS–DRGs) are posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html.*

For this FY 2020 IPPS/LTCH PPS proposed rule, below we address the MCE requests we received by the November 1, 2018 deadline. We also discuss the proposals we are making based on our internal review and analysis.

a. Age Conflict Edit: Maternity Diagnoses

In the MCE, the Age conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age conflict edit and are listed in the manual and written in the software program:

- Perinatal/Newborn—Age of 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 (for example, tetanus neonatorum, health examination for newborn under 8 days old).
- Pediatric—Age is 0–17 years inclusive (for example, Reye's syndrome, routine child health exam).
- Maternity—Age range is 12–55 years inclusive (for example, diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15–124 years inclusive (for example, senile delirium, mature cataract).

Under the ICD–10 MCE, the maternity diagnoses category for the Age conflict edit considers the age range of 12 to 55 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

We received a request to reconsider the age range associated with the maternity diagnoses category for the Age conflict edit. According to the requestor, pregnancies can and do occur prior to age 12 and after age 55. The requestor suggested that a more appropriate age range would be from age 9 to age 64 for the maternity diagnoses category.

We agree with the requestor that pregnancies can and do occur prior to the age of 12 and after the age of 55. We also agree that the suggested range, age 9 to age 64, is an appropriate age range. Therefore, we are proposing to revise the maternity diagnoses category for the Age conflict edit to consider the new age range of 9 to 64 years inclusive.

b. Sex Conflict Edit: Diagnoses for Females Only Edit

In the MCE, the Sex conflict edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record; for example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient's diagnosis, procedure, or sex is presumed to be incorrect.

As discussed in section II.F.15. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes which is associated with this proposed rule (and is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2019. ICD–10–CM diagnosis code N99.85 (Post endometrial ablation syndrome) is a new code that describes a condition consistent with the female sex. We are proposing to add this diagnosis code to the Diagnoses for Females Only edit code list under the Sex conflict edit.

c. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance that influences an individual's health status but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable Principal Diagnosis edit code list that are considered ''acceptable'' when a specified secondary diagnosis is also coded and reported on the claim.

ICD–10–CM diagnosis codes I46.2 (Cardiac arrest due to underlying cardiac condition) and I46.8 (Cardiac arrest due to other underlying condition) are codes that clearly specify cardiac arrest as being due to an underlying condition. Also, in the ICD–10–CM Tabular List, there are instructional notes to ''Code first underlying cardiac condition'' at ICD–10–CM diagnosis code I46.2 and to ''Code first underlying condition'' at ICD–10–CM diagnosis code I46.8. Therefore, we are proposing to add ICD–10–CM diagnosis codes I46.2 and I46.8 to the Unacceptable Principal Diagnosis Category edit code list.

As discussed in section II.F.15. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes associated with this proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the new diagnosis

codes that have been approved to date that will be effective with discharges occurring on and after October 1, 2019.

We are proposing to add the new ICD–10–CM diagnosis codes listed in the following table to the Unacceptable Principal Diagnosis Category edit code list, as these codes are consistent with other ICD–10–CM diagnosis codes currently included on the Unacceptable Principal Diagnosis Category edit code list.

ICD–10–CM code	Code description
T50.915A	Adverse effect of multiple unspecified drugs, medicaments and biological substances, initial encounter.
T50.915D	Adverse effect of multiple unspecified drugs, medicaments and biological substances, subsequent encounter.
T50.915S	Adverse effect of multiple unspecified drugs, medicaments and biological substances, sequela.
T50.916A	Underdosing of multiple unspecified drugs, medicaments and biological substances, initial encounter.
T50.916D	Underdosing of multiple unspecified drugs, medicaments and biological substances, subsequent encounter.
T50.916S	Underdosing of multiple unspecified drugs, medicaments and biological substances, sequela.
Z11.7	Encounter for testing for latent tuberculosis infection.
Z22.7	Latent tuberculosis.
Z71.84	Encounter for health counseling related to travel.
Z86.002	Personal history of in-situ neoplasm of other and unspecified genital organs.
Z86.003	Personal history of in-situ neoplasm of oral cavity, esophagus and stomach.
Z86.004	Personal history of in-situ neoplasm of other and unspecified digestive organs.
Z86.005	Personal history of in-situ neoplasm of middle ear and respiratory system.
Z86.006	Personal history of melanoma in-situ.

d. Non-Covered Procedure Edit

In the MCE, the Non-Covered Procedure edit identifies procedures for which Medicare does not provide payment. Payment is not provided due to specific criteria that are established in the National Coverage Determination (NCD) process. We refer readers to the website at: *https://www.cms.gov/Medicare/Coverage/DeterminationProcess/howtorequestanNCD.html* for additional information on this process. In addition, there are procedures that would normally not be paid by Medicare but, due to the presence of certain diagnoses, are paid.

As discussed in section II.F.15. of the preamble of this proposed rule, Table 6D.—Invalid Procedure Codes associated with this proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the procedure codes that are no longer effective as of October 1, 2019. Included in this table are the following ICD–10–PCS procedure codes listed on the Non-Covered Procedure edit code list.

ICD–10–PCS code	Code description
037G3Z6	Dilation of intracranial artery, bifurcation, percutaneous approach.
037G4Z6	Dilation of intracranial artery, bifurcation, percutaneous endoscopic approach.

We are proposing to remove these codes from the Non-Covered Procedure edit code list. In addition, as discussed in section II.F.2.b. of the preamble of this proposed rule, a number of ICD–10–PCS procedure codes describing bone marrow transplant procedures were the subject of a proposal discussed at the March 5–6, 2019 ICD–10 Coordination and Maintenance Committee meeting, to be deleted effective October 1, 2019. We are proposing that if the applicable proposal is finalized, we would delete the subset of those ICD–10–PCS procedure codes that are currently listed on the Non-Covered Procedure edit code list as shown in the following table.

ICD–10–PCS code	Code description
30250G0	Transfusion of autologous bone marrow into peripheral artery, open approach.
30250Y0	Transfusion of autologous hematopoietic stem cells into peripheral artery, open approach.
30253G0	Transfusion of autologous bone marrow into peripheral artery, percutaneous approach.
30253Y0	Transfusion of autologous hematopoietic stem cells into peripheral artery, percutaneous approach.
30260G0	Transfusion of autologous bone marrow into central artery, open approach.
30260Y0	Transfusion of autologous hematopoietic stem cells into central artery, open approach.
30263G0	Transfusion of autologous bone marrow into central artery, percutaneous approach.
30263Y0	Transfusion of autologous hematopoietic stem cells into central artery, percutaneous approach.

e. Future Enhancement

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38053 through 38054), we noted the importance of ensuring accuracy of the coded data from the reporting, collection, processing, coverage, payment, and analysis aspects. We have engaged a contractor to assist in the review of the limited coverage and noncovered procedure edits in the MCE that may also be present in other claims processing systems that are utilized by our MACs. The MACs must adhere to criteria specified within the National Coverage Determinations (NCDs) and may implement their own edits in addition to what are already incorporated into the MCE, resulting in duplicate edits. The objective of this review is to identify where duplicate edits may exist and to determine what the impact might be if these edits were to be removed from the MCE.

We have noted that the purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. As we indicated in the FY 2019 IPPS/LTCH PPS final rule (83 FR

41228), we are considering whether the inclusion of coverage edits in the MCE necessarily aligns with that specific goal because the focus of coverage edits is on whether or not a particular service is covered for payment purposes and not whether it was coded correctly.

As we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion. As we have discussed in prior rulemaking, we recognize a need to further examine the current list of edits and the definitions of those edits. We continue to encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to the MS–DRG Classification Change Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2019 for the FY 2021 rulemaking.

17. Proposed Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this proposed rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we are proposing to make in this FY 2020 IPPS/LTCH PPS proposed rule, as discussed in section II.F.5. of this preamble of this proposed rule, we are proposing to revise the surgical hierarchy for MDC 5 (Diseases and Disorders of the Circulatory System) as follows: In MDC 5, we are proposing to sequence proposed new MS–DRGs 319 and 320 (Other Endovascular Cardiac Valve Procedures with and without MCC, respectively) above MS–DRGs 222, 223, 224, 225, 226, and 227 (Cardiac Defibrillator Implant with and without Cardiac Catheterization with and without AMI/HF/Shock with and without MCC, respectively) and below MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with and without MCC, respectively). We also note that, as discussed in section II.F.5.a. of this preamble of this proposed rule, we are proposing to revise the titles for MS–DRGs 266 and 267 to ''Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC'' and ''Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC'', respectively.

Our proposal for Appendix D—MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 37 is illustrated in the following table.

PROPOSED SURGICAL HIERARCHY: MDC 5

MS–DRG 215	Other Heart Assist System Implant.
MS–DRGs 216–221	Cardiac Valve and Other Major Cardiothoracic Procedures.
MS–DRGs 266 and 267	Endovascular Cardiac Valve Procedures.
Proposed New MS–DRGs 319 and 320	Other Endovascular Cardiac Valve Procedures.
MS–DRGs 222–227	Cardiac Defibrillator Implant.

As with other MS–DRG related issues, we encourage commenters to submit requests to examine ICD–10 claims pertaining to the surgical hierarchy via the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2019 for consideration for FY 2021.

18. Maintenance of the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention (CDC), and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html.* The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html.*

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the previously mentioned process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2020 at a public meeting held on September 11–12, 2018, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 13, 2018.

The Committee held its 2019 meeting on March 5–6, 2019. The deadline for submitting comments on these code proposals is scheduled for April 5, 2019. It was announced at this meeting that any new diagnosis and procedure codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by May 2019 would be included in the October 1, 2019 update to the ICD–10–CM diagnosis and ICD–10–PCS procedure code sets. As discussed in earlier sections of the preamble of this proposed rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for this proposed rule, which are available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* The code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we make the code titles available for the IPPS proposed rule, they are not subject to comment in the proposed rule. Because of the length of these tables, they are not published in the Addendum to the proposed rule. Rather, they are available via the internet as discussed in section VI. of the Addendum to this proposed rule.

Live Webcast recordings of the discussions of the diagnosis and procedure codes at the Committee's September 11–12, 2018 meeting can be obtained from the CMS website at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/03_meetings.asp.* The live webcast recordings of the discussions of the diagnosis and procedure codes at the Committee's March 5–6, 2019 meeting can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html.*

The materials for the discussions relating to diagnosis codes at the September 11–12 2018 meeting and March 5–6, 2019 meeting can be found at: *http://www.cdc.gov/nchs/icd/icd10cm_maintenance.html.* These websites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by Email to: *nchsicd10cm@cdc.gov.*

Questions and comments concerning the procedure codes should be submitted via Email to: *ICDProcedureCodeRequest@cms.hhs.gov.*

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies

at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 3 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS website. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS websites in June of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requestor at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting materials and live webcast are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were not any requests approved for an expedited April l, 2019 implementation of a code at the September 11–12, 2018 Committee meeting. Therefore, there were not any new codes for implementation on April 1, 2019.

ICD–9–CM addendum and code title information is published on the CMS website at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage.* ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html.* CMS also sends copies of all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can also be found on the CDC website at: *http://www.cdc.gov/nchs/icd/icd10.htm.* Additionally, information on new, revised, and deleted ICD–10–CM diagnosis and ICD–10–PCS procedure codes is provided to the AHA for publication in the *Coding Clinic for ICD–10.* AHA also distributes coding update information to publishers and software vendors.

The following chart shows the number of ICD–10–CM and ICD–10–PCS codes and code changes since FY 2016 when ICD–10 was implemented.

TOTAL NUMBER OF CODES AND CHANGES IN TOTAL NUMBER OF CODES PER FISCAL YEAR ICD–10–CM AND ICD–10–PCS CODES

Fiscal year	Number	Change
FY 2016:		
ICD–10–CM	69,823	.....
ICD–10–PCS	71,974	.....
FY 2017:		
ICD–10–CM	71,486	+1,663
ICD–10–PCS	75,789	+3,815
FY 2018:		
ICD–10–CM	71,704	+218
ICD–10–PCS	78,705	+2,916
FY 2019:		
ICD–10–CM	71,932	+228
ICD–10–PCS	78,881	+176
FY 2020 (Proposed):		
ICD–10–CM	72,184	+252
ICD–10–PCS	77,221	−1,660

As mentioned previously, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting.

19. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Proposed Changes for FY 2020

As discussed in section II.F.5.a. of the preamble of this proposed rule, for FY 2020, we are proposing to create new MS–DRGs 319 and 320 (Other Endovascular Cardiac Valve Procedures with and without MCC, respectively) and to revise the title for MS–DRG 266 from ''Endovascular Cardiac Valve Replacement with MCC'' to

''Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC'' and the title for MS–DRG 267 from ''Endovascular Cardiac Valve Replacement without MCC'' to ''Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC''.

As stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24409), we generally map new MS–DRGs onto the list when they are formed from procedures previously assigned to MS–DRGs that are already on the list. Currently, MS–DRGs 216 through 221 are on the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit as shown in the table below. A subset of the procedures currently assigned to MS–DRGs 216 through 221 is being proposed for assignment to proposed new MS–DRGs 319 and 320. Therefore, we are proposing that if the applicable proposed MS–DRG changes are finalized, we also would add proposed new MS–DRGs 319 and 320 to the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit and make conforming changes to the titles of MS–DRGs 266 and 267 as reflected in the table below. We also are proposing to continue to include the existing MS–DRGs currently subject to the policy as also displayed in the table below.

MDC	MS–DRG	MS–DRG title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC.
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC.
1	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator.
1	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC.
1	025	Craniotomy & Endovascular Intracranial Procedures with MCC.
1	026	Craniotomy & Endovascular Intracranial Procedures with CC.
1	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC.
1	040	Peripheral, Cranial Nerve & Other Nervous System Procedures with MCC.
1	041	Peripheral, Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulator.
1	042	Peripheral, Cranial Nerve & Other Nervous System Procedures without CC/MCC.
3	129	Major Head & Neck Procedures with CC/MCC or Major Device.
3	130	Major Head & Neck Procedures without CC/MCC.
5	215	Other Heart Assist System Implant.
5	216	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC.
5	217	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC.
5	218	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC.
5	219	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC.
5	220	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC.
5	221	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC.
5	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC.
5	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC.
5	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC.
5	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC.
5	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC.
5	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC.
5	242	Permanent Cardiac Pacemaker Implant with MCC.
5	243	Permanent Cardiac Pacemaker Implant with CC.
5	244	Permanent Cardiac Pacemaker Implant without CC/MCC.
5	245	AICD Generator Procedures.
5	258	Cardiac Pacemaker Device Replacement with MCC.
5	259	Cardiac Pacemaker Device Replacement without MCC.
5	260	Cardiac Pacemaker Revision Except Device Replacement with MCC.
5	261	Cardiac Pacemaker Revision Except Device Replacement with CC.
5	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC.
5	265	AICD Lead Procedures.
5	266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC.
5	267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC.
5	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
5	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
5	270	Other Major Cardiovascular Procedures with MCC.
5	271	Other Major Cardiovascular Procedures with CC.
5	272	Other Major Cardiovascular Procedures without CC/MCC.
5	319	Other Endovascular Cardiac Valve Procedures with MCC.
5	320	Other Endovascular Cardiac Valve Procedures without MCC.
8	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC.
8	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC.
8	466	Revision of Hip or Knee Replacement with MCC.
8	467	Revision of Hip or Knee Replacement with CC.
8	468	Revision of Hip or Knee Replacement without CC/MCC.
8	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement.
8	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC.

The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be included in the FY 2020 IPPS/LTCH PPS final rule and also will be issued to

providers in the form of a Change Request (CR).

G. Recalibration of the Proposed FY 2020 MS–DRG Relative Weights

1. Data Sources for Developing the Proposed Relative Weights

In developing the proposed FY 2020 system of weights, we are proposing to use two data sources: Claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2018 MedPAR data used in this proposed rule include discharges occurring on October 1, 2017, through September 30, 2018, based on bills received by CMS through December 31, 2018, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). The FY 2018 MedPAR file used in calculating the proposed relative weights includes data for approximately 9,480,820 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 31, 2018 update of the FY 2018 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the proposed relative weights for FY 2020 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the proposed FY 2020 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2018 MedPAR claims data, grouped through the ICD–10 version of the proposed FY 2020 GROUPER (Version 37).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, we used cost report data from the December 31, 2018 update of the FY 2017 HCRIS for calculating the proposed FY 2020 cost-based relative weights.

2. Methodology for Calculation of the Proposed Relative Weights

As we explain in section II.E.2. of the preamble of this proposed rule, we calculated the proposed FY 2020 relative weights based on 19 CCRs, as we did for FY 2019. The methodology we are proposing to use to calculate the FY 2020 MS–DRG cost-based relative weights based on claims data in the FY 2018 MedPAR file and data from the FY 2017 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2020 MS–DRG classifications discussed in sections II.B. and II.F. of the preamble of this proposed rule.
- The transplant cases that were used to establish the proposed relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2018 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.
- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.
- At least 92.3 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative

weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (77 FR 53341 through 53343). Specifically, because acute care hospitals participating in the BPCI Initiative still receive IPPS payments under section 1886(d) of the Act, we include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations as if the hospitals were not participating in those models under the BPCI initiative. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's website at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The participation of hospitals in the BPCI initiative concluded on September 30, 2018. The participation of hospitals in the Bundled Payments for Care Improvement (BPCI) Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in BPCI Advanced in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/.* Consistent with our policy for FY 2019, and consistent with how we have treated hospitals that participated in the BPCI Initiative, for FY 2020, we continue to believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because, as noted above, these hospitals are still receiving IPPS payments under section 1886(d) of the Act.

The charges for each of the proposed 19 cost groups for each claim were standardized to remove the effects of differences in proposed area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable proposed cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in proposed geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the proposed 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the proposed national average CCRs developed from the FY 2017 cost report data.

The proposed 19 cost centers that we used in the proposed relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the proposed 19 national cost center CCRs. If stakeholders have comments about the groupings in this table, we may consider those comments as we finalize our policy.

We are inviting public comments on our proposals related to recalibration of the proposed FY 2020 relative weights and the changes in relative weights from FY 2019.

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Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Routine Days	Private Room Charges	011X and 014X		Adults & Pediatrics (General Routine Care)	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30
	Semi-Private Room Charges	012X, 013X and 016X					
	Ward Charges	015X					
Intensive Days	Intensive Care Charges	020X		Intensive Care Unit	C_1_C5_31	C_1_C6_31	D3_HOS_C2_31
	Coronary Care Charges	021X		Coronary Care Unit	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Burn Intensive Care Unit	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
				Surgical Intensive Care Unit	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
				Other Special Care Unit	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges	025X, 026X and 063X		Intravenous Therapy	C_1_C5_64	C_1_C6_64	D3_HOS_C2_64
						C_1_C7_64	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Drugs Charged To Patient	C_1_C5_73	C_1_C6_73	D3_HOS_C2_73
						C_1_C7_73	
Supplies and Equipment	Medical/Surgical Supply Charges	0270, 0271, 0272, 0273, 0274, 0277, 0279, and 0621, 0622, 0623		Medical Supplies Charged to Patients	C_1_C5_71	C_1_C6_71	D3_HOS_C2_71
						C_1_C7_71	
	Durable Medical Equipment Charges	0290, 0291, 0292 and 0294-0299		DME-Rented	C_1_C5_96	C_1_C6_96	D3_HOS_C2_96
						C_1_C7_96	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Used Durable Medical Charges	0293		DME-Sold	C_1_C5_97	C_1_C6_97	D3_HOS_C2_97
						C_1_C7_97	
Implantable Devices		0275, 0276, 0278, 0624		Implantable Devices Charged to Patients	C_1_C5_72	C_1_C6_72	D3_HOS_C2_72
						C_1_C7_72	
Therapy Services	Physical Therapy Charges	042X		Physical Therapy	C_1_C5_66	C_1_C6_66	D3_HOS_C2_66
						C_1_C7_66	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Occupational Therapy Charges	043X		Occupational Therapy	C_1_C5_67	C_1_C6_67	D3_HOS_C2_67
						C_1_C7_67	
	Speech Pathology Charges	044X and 047X		Speech Pathology	C_1_C5_68	C_1_C6_68	D3_HOS_C2_68
						C_1_C7_68	
Inhalation Therapy	Inhalation Therapy Charges	041X and 046X		Respiratory Therapy	C_1_C5_65	C_1_C6_65	D3_HOS_C2_65
						C_1_C7_65	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Operating Room	Operating Room Charges	036X		Operating Room	C_1_C5_50	C_1_C6_50	D3_HOS_C2_50
						C_1_C7_50	
		071X		Recovery Room	C_1_C5_51	C_1_C6_51	D3_HOS_C2_51
						C_1_C7_51	
Labor & Delivery	Operating Room Charges	072X		Delivery Room and Labor Room	C_1_C5_52	C_1_C6_52	D3_HOS_C2_52
						C_1_C7_52	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Anesthesia	Anesthesia Charges	037X		Anesthesi-ology	C_1_C5_53	C_1_C6_53	D3_HOS_C2_53
						C_1_C7_53	
Cardiology	Cardiology Charges	048X and 073X		Electro-cardiology	C_1_C5_69	C_1_C6_69	D3_HOS_C2_69
						C_1_C7_69	
Cardiac Catheteri-zation		0481		Cardiac Catheterization	C_1_C5_59	C_1_C6_59	D3_HOS_C2_59
						C_1_C7_59	
Laboratory	Laboratory Charges	030X, 031X, and 075X		Laboratory	C_1_C5_60	C_1_C6_60	D3_HOS_C2_60

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_60	
				PBP Clinic Laboratory Services	C_1_C5_61	C_1_C6_61	D3_HOS_C2_61
						C_1_C7_61	
		074X, 086X		Electro-Encephalography	C_1_C5_70	C_1_C6_70	D3_HOS_C2_70
						C_1_C7_70	
Radiology	Radiology Charges	032X, 040X		Radiology – Diagnostic	C_1_C5_54	C_1_C6_54	D3_HOS_C2_54
						C_1_C7_54	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
		028x, 0331, 0332, 0333, 0335, 0339, 0342		Radiology – Therapeutic	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344		Radioisotope	C_1_C5_56	C_1_C6_56	D3_HOS_C2_56
						C_1_C7_56	
Computed Tomography (CT) Scan	CT Scan Charges	035X		Computed Tomography (CT) Scan	C_1_C5_57	C_1_C6_57	D3_HOS_C2_57
						C_1_C7_57	
Magnetic Resonance Imaging (MRI)	MRI Charges	061X		Magnetic Resonance Imaging (MRI)	C_1_C5_58	C_1_C6_58	D3_HOS_C2_58
						C_1_C7_58	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Emergency Room	Emergency Room Charges	045x		Emergency	C_1_C5_91	C_1_C6_91	D3_HOS_C2_91
						C_1_C7_91	
Blood and Blood Products	Blood Charges	038x		Whole Blood & Packed Red Blood Cells	C_1_C5_62	C_1_C6_62	D3_HOS_C2_62
						C_1_C7_62	
	Blood Storage / Processing	039x		Blood Storing, Processing, & Transfusing	C_1_C5_63	C_1_C6_63	D3_HOS_C2_63
						C_1_C7_63	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Other Services	Other Service Charge	0002-0099, 022X, 023X, 024X,052X, 053X					
		055X-060X, 064X-070X, 076X-078X, 090X-095X and 099X					
	Renal Dialysis	0800X		Renal Dialysis	C_1_C5_74	C_1_C6_74	D3_HOS_C2_74
	ESRD Revenue Setting Charges	080X and 082X-088X				C_1_C7_74	
				Home Program Dialysis	C_1_C5_94	C_1_C6_94	D3_HOS_C2_94

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_94	
	Outpatient Service Charges	049X		ASC (Non Distinct Part)	C_1_C5_75	C_1_C6_75	D3_HOS_C2_75
	Lithotripsy Charge	079X				C_1_C7_75	
				Other Ancillary	C_1_C5_76	C_1_C6_76	D3_HOS_C2_76
						C_1_C7_76	
	Clinic Visit Charges	051X		Clinic	C_1_C5_90	C_1_C6_90	D3_HOS_C2_90
						C_1_C7_90	
				Observation beds	C_1_C5_92.01	C_1_C6_92.01	D3_HOS_C2_92.01
						C_1_C7_92.01	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Professional Fees Charges	096X, 097X, and 098X		Other Outpatient Services	C_1_C5_93	C_1_C6_93	D3_HOS_C2_93
						C_1_C7_93	
	Ambulance Charges	054X		Ambulance	C_1_C5_95	C_1_C6_95	D3_HOS_C2_95
						C_1_C7_95	
				Rural Health Clinic	C_1_C5_88	C_1_C6_88	D3_HOS_C2_88
						C_1_C7_88	
				FQHC	C_1_C5_89	C_1_C6_89	D3_HOS_C2_89
						C_1_C7_89	

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3. Development of Proposed National Average CCRs

We developed the proposed national average CCRs as follows:

Using the FY 2017 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater

than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the proposed 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each proposed MS–DRG to produce a total standardized cost for the proposed MS–DRG. The average standardized cost for each proposed MS–DRG was then computed as the total standardized cost for the proposed MS–DRG divided by the transfer-adjusted case count for the proposed MS–DRG. The average cost for each proposed MS–DRG was then divided by the national average standardized cost per case to determine the proposed relative weight.

The proposed FY 2020 cost-based relative weights were then normalized by a proposed adjustment factor of 1.788337 so that the average case weight after recalibration was equal to the average case weight before recalibration. The proposed normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The proposed 19 national average CCRs for FY 2020 are as follows:

Group	CCR
Routine Days	0.433
Intensive Days	0.362
Drugs	0.191
Supplies & Equipment	0.301
Implantable Devices	0.308
Therapy Services	0.297
Laboratory	0.109
Operating Room	0.175
Cardiology	0.099
Cardiac Catheterization	0.106
Radiology	0.140
MRIs	0.073
CT Scans	0.035
Emergency Room	0.154
Blood and Blood Products	0.282
Other Services	0.344
Labor & Delivery	0.369
Inhalation Therapy	0.151
Anesthesia	0.077

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We are proposing to use that same case threshold in recalibrating the proposed MS–DRG relative weights for FY 2020. Using data from the FY 2018 MedPAR file, there were 8 MS–DRGs that contain fewer than 10 cases. For FY 2020, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we are proposing to compute relative weights for the proposed low-volume MS–DRGs by adjusting their final FY 2019 relative weights by the percentage change in the average weight of the cases in other MS–DRGs from FY 2019 to FY 2020. The crosswalk table is shown below.

Low-volume MS–DRG	MS–DRG title	Crosswalk to MS–DRG
338	Appendectomy with Complicated Principal Diagnosis with MCC.	Final FY 2019 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
789	Neonates, Died or Transferred to Another Acute Care Facility.	Final FY 2019 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate.	Final FY 2019 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	Final FY 2019 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	Final FY 2019 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
793	Full-Term Neonate with Major Problems	Final FY 2019 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	Final FY 2019 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
795	Normal Newborn	Final FY 2019 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

H. Proposed Add-On Payments for New Services and Technologies for FY 2020

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. We note that, beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs. The regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the

DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Below we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For a complete discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will be considered ''new'' for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold amounts. The MS–DRG threshold amounts used in evaluating new technology add-on payment applications for FY 2020 are presented in a data file that is available, along with the other data files associated with the FY 2019 IPPS/LTCH PPS final rule and correction notice, on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Final-Rule-Home-Page-Items/FY2019-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.* As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the proposed thresholds for applications for new technology add-on payments for FY 2021 are presented in a data file that is available on the CMS website, along with the other data files associated with this FY 2020 proposed rule, by clicking on the FY 2020 IPPS Proposed Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

Under the third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available. (We refer readers to the September 7, 2001 final rule for a more detailed discussion of this criterion (66 FR 46902). We also refer readers to section II.H.8. of the preamble of this proposed rule for a discussion of our proposed alternative inpatient new technology add-on payment pathway for transformative new devices.)

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Under § 412.88, if the costs of the discharge (determined by applying cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology or medical service (if the estimated costs for the case including the new technology or medical service exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology or medical service. We refer readers to section II.H.9. of the preamble of this proposed rule for a discussion of our proposed change to the calculation of the new technology add-on payment beginning in FY 2020, including our proposed amendments to § 412.88 of the regulations.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new

medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We amended § 412.87(c) to specify that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

The Council on Technology and Innovation (CTI) at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies and medical services between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local Medicare Administrative Contractors (MACs) (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an ''Innovator's Guide'' to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS website, in a user friendly format. This guide was published in 2010 and is available on the CMS website at: *https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf.*

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical services or technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov.*

We note that applicants for add-on payments for new medical services or technologies for FY 2021 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2021, the CMS website also will post the tracking forms completed by each applicant. We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the PRA; it is currently approved under OMB control number 0938–1347, which expires on December 31, 2020.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2020 prior to publication of this FY 2020 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on October 5, 2018 (83 FR 50379), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on December 4, 2018. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for each of the FY 2020 new medical service and technology add-on payment applications before the publication of the FY 2020 IPPS/LTCH PPS proposed rule.

Approximately 100 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open

telephone line. We also live-streamed the town hall meeting and posted the morning and afternoon sessions of the town hall on the CMS YouTube web page at: *https://www.youtube.com/watch?v=4z1AhEuGHqQ and https://www.youtube.com/watch?v=m26Xj1EzbIY,* respectively. We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of December 14, 2018, in our evaluation of the new technology add-on payment applications for FY 2020 in this FY 2020 IPPS/LTCH PPS proposed rule.

In response to the published notice and the December 4, 2018 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2020 new technology add-on payments. We note that we do not summarize comments that are unrelated to the ''substantial clinical improvement'' criterion. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (83 FR 50379 through 50381), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2020. Therefore, we are not summarizing those written comments in this proposed rule that are unrelated to the substantial clinical improvement criterion. In section II.H.5. of the preamble of this FY 2020 IPPS/LTCH PPS proposed rule, we are summarizing comments regarding individual applications, or, if applicable, indicating that there were no comments received in response to the New Technology Town Hall meeting notice, at the end of each discussion of the individual applications.

Comment: One commenter expressed appreciation for CMS' statements in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20278 through 20279) relating to the similarity between data that satisfy the FDA's designations and data that satisfy the substantial clinical improvement criterion under the new technology add-on payment policy. The commenter stated that clarity was provided that will help future applicants understand which types of data can serve as the foundation for satisfying the substantial clinical improvement criterion. The commenter also expressed its appreciation that CMS further clarified that it accepts a wide range of data that would support the conclusion that the technology represents a substantial clinical improvement. The commenter explained that it interpreted CMS' statements to mean that CMS appreciates and considers the patient's experience and point-of-view in its determination of a technology's substantial clinical improvement with respect to existing technologies, and stated that it hopes the agency will confirm this rationale in upcoming rulemaking.

Response: We appreciate the commenter's support of our clarifying statements in the FY 2019 IPPS/LTCH PPS proposed rule. Additionally, we refer the commenter to the September 7, 2001 final rule for a more detailed discussion of the substantial clinical improvement criterion (66 FR 46902). We also refer readers to section II.H.8. of the preamble of this proposed rule for a discussion of our proposed alternative inpatient new technology add-on payment pathway for transformative new devices, and sections II.H.6. and II.H.7. of the preamble of this proposed rule for a discussion of and request for comment on potential revisions to the new technology add-on payment substantial clinical improvement criterion.

Comment: Another commenter stated that the criteria for priority FDA review are very similar to the criteria to substantiate a technology's substantial clinical improvement under the new technology add-on payment policy and, therefore, devices used in the inpatient setting that are determined to be eligible for expedited review and approved by the FDA should automatically be considered as representing a substantial clinical improvement with respect to existing technologies, without further consideration by CMS.

Response: We refer readers to our response to this and similar comments in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20278 through 20279).

Comment: One commenter stated that an entity submitting an application for new technology add-on payments should be entitled to administrative review of an adverse determination by an official of the Department of Health and Human Services other than an official of the CMS. The commenter believed that this will provide a safeguard both for the manufacturer submitting an application, as well as for beneficiaries who would benefit from access to the innovative technology that is the subject of the new technology add-on payment application. The commenter further recommended that administrative review of an adverse determination should not preclude resubmission of a modified application at a later point in the future.

Response: As discussed previously, the public has an opportunity at the New Technology Town Hall meeting to provide input regarding the substantial clinical improvement criterion for each new technology add-on payment application under review for the upcoming fiscal year. We summarize each application in the IPPS/LTCH PPS proposed rule, and consider the public comments received in response to the proposed rule in determining whether to approve an application for new technology add-on payments. Furthermore, we also accept additional supplemental information on all new technology add-on payment applications summarized in the proposed rule through the end of the comment period for the annual IPPS/LTCH PPS proposed rule. We conduct a thorough review of all applications and, as described above, allow a wide range of data that would support the conclusion of a representation of substantial clinical improvement. We also note that an applicant may always resubmit an application for new technology add-on payments for a subsequent year following a denial of an application submitted for a prior fiscal year.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html,* including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

4. Proposed FY 2020 Status of Technologies Approved for FY 2019 New Technology Add-On Payments

a. Defitelio® (Defibrotide)

Jazz Pharmaceuticals submitted an application for new technology add-on payments for FY 2017 for defibrotide (Defitelio®), a treatment for patients who have been diagnosed with hepatic veno-occlusive disease (VOD) with evidence of multi-organ dysfunction. VOD, also known as sinusoidal obstruction syndrome (SOS), is a potentially life-threatening complication of hematopoietic stem cell transplantation (HSCT), with an incidence rate of 8 percent to 15 percent. Diagnoses of VOD range in severity from what has been classically defined as a disease limited to the liver (mild) and reversible, to a severe syndrome associated with multi-organ dysfunction or failure and death. Patients who have received treatment involving HSCT who develop VOD with multi-organ failure face an immediate risk of death, with a mortality rate of more than 80 percent when only supportive care is used. The applicant asserted that Defitelio® improves the survival rate of patients who have been diagnosed with VOD with multi-organ failure by 23 percent.

Defitelio® received Orphan Drug Designation for the treatment of VOD in 2003 and for the prevention of VOD in 2007. It has been available to patients as an investigational drug through an Expanded Access Program since 2006. The applicant's New Drug Application (NDA) for Defitelio® received FDA approval on March 30, 2016. The applicant confirmed that Defitelio® was not available on the U.S. market as of the FDA NDA approval date of March 30, 2016. According to the applicant, commercial packaging could not be completed until the label for Defitelio® was finalized with FDA approval, and that commercial shipments of Defitelio® to hospitals and treatment centers began on April 4, 2016. Therefore, we agreed that, based on this information, the newness period for Defitelio® begins on April 4, 2016, the date of its first commercial availability.

The applicant received approval to use unique ICD–10–PCS procedure codes to describe the use of Defitelio®, with an effective date of October 1, 2016. The approved ICD–10–PCS procedure codes are: XW03392 (Introduction of defibrotide sodium anticoagulant into peripheral vein, percutaneous approach); and XW04392 (Introduction of defibrotide sodium anticoagulant into central vein, percutaneous approach). After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for Defitelio® and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved Defitelio® for new technology add-on payments for FY 2017 (81 FR 56906). With the new technology add-on payment application, the applicant estimated that the average Medicare beneficiary would require a dosage of 25 mg/kg/day for a minimum of 21 days of treatment. The recommended dose is 6.25 mg/kg given as a 2-hour intravenous infusion every 6 hours. Dosing should be based on a patient's baseline body weight, which is assumed to be 70 kg for an average adult patient. All vials contain 200 mg at a cost of $825 per vial. Therefore, we determined that cases involving the use of the Defitelio® technology would incur an average cost per case of $151,800 (70 kg adult × 25 mg/kg/day × 21 days = 36,750 mg per patient/200 mg vial = 184 vials per patient × $825 per vial = $151,800). Under existing § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of Defitelio® is $75,900 for FY 2019.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

With regard to the newness criterion for Defitelio®, we considered the beginning of the newness period to commence on the first day Defitelio® was commercially available (April 4, 2016). Because the 3-year anniversary date of the entry of the Defitelio® onto the U.S. market (April 4, 2019) will occur during FY 2019, we are proposing to discontinue new technology add-on payments for this technology for FY 2020. We are inviting public comments on our proposal to discontinue new technology add-on payments for Defitelio® for FY 2020.

b. Ustekinumab (Stelara®)

Janssen Biotech submitted an application for new technology add-on payments for the Stelara® induction therapy for FY 2018. Stelara® received FDA approval on September 23, 2016 as an intravenous (IV) infusion treatment for adult patients who have been diagnosed with moderately to severely active Crohn's disease (CD) who have failed or were intolerant to treatment using immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker, or failed or were intolerant to treatment using one or more TNF blockers. Stelara® IV is intended for induction—subcutaneous prefilled syringes are intended for maintenance dosing. Stelara® must be administered intravenously by a health care professional in either an inpatient hospital setting or an outpatient hospital setting.

Stelara® for IV infusion is packaged in single 130 mg vials. Induction therapy consists of a single IV infusion dose using the following weight-based dosing regimen: Patients weighing 55 kg or less than (<) 55 kg are administered 260 mg of Stelara® (2 vials); patients weighing more than (>) 55 kg, but 85 kg or less than (<) 85 kg are administered 390 mg of Stelara® (3 vials); and patients weighing more than (>) 85 kg are administered 520 mg of Stelara® (4 vials). An average dose of Stelara® administered through IV infusion is 390 mg (3 vials). Maintenance doses of Stelara® are administered at 90 mg, subcutaneously, at 8-week intervals and may occur in the outpatient hospital setting.

CD is an inflammatory bowel disease of unknown etiology, characterized by transmural inflammation of the gastrointestinal (GI) tract. Symptoms of CD may include fatigue, prolonged diarrhea with or without bleeding, abdominal pain, weight loss and fever. CD can affect any part of the GI tract including the mouth, esophagus, stomach, small intestine, and large intestine. Most commonly used pharmacologic treatments for CD include antibiotics, mesalamines, corticosteroids, immunomodulators, tumor necrosis alpha (TNFα) inhibitors, and anti-integrin agents. Surgery may be necessary for some patients who have been diagnosed with CD in which conventional therapies have failed. After evaluation of the newness, costs,

and substantial clinical improvement criteria for new technology add-on payments for Stelara® and consideration of the public comments we received in response to the FY 2018 IPPS/LTCH PPS proposed rule, we approved Stelara® for new technology add-on payments for FY 2018 (82 FR 38129). Cases involving Stelara® that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure code XW033F3 (Introduction of other New Technology therapeutic substance into peripheral vein, percutaneous approach, new technology group 3). With the new technology add-on payment application, the applicant estimated that the average Medicare beneficiary would require a dosage of 390 mg (3 vials) at a hospital acquisition cost of $1,600 per vial (for a total of $4,800). Under existing § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of Stelara® is $2,400 for FY 2019.

With regard to the newness criterion for Stelara®, we considered the beginning of the newness period to commence when Stelara® received FDA approval as an IV infusion treatment for Crohn's disease (CD) on September 23, 2016. Because the 3-year anniversary date of the entry of Stelara® onto the U.S. market (September 23, 2019) will occur during FY 2019, we are proposing to discontinue new technology add-on payments for this technology for FY 2020. We are inviting public comments on our proposal to discontinue new technology add-on payments for Stelara® for FY 2020.

c. Bezlotoxumab (ZINPLAVA™)

Merck & Co., Inc. submitted an application for new technology add-on payments for ZINPLAVA™ for FY 2018. ZINPLAVA™ is indicated as a treatment to reduce recurrence of Clostridium difficile infection (CDI) in adult patients who are receiving antibacterial drug treatment for a diagnosis of CDI and who are at high risk for CDI recurrence. ZINPLAVA™ is not indicated for the treatment of the presenting episode of CDI and is not an antibacterial drug. ZINPLAVA™ should only be used in conjunction with an antibacterial drug treatment for CDI.

Clostridium difficile (*C-diff*) is a disease-causing anaerobic, spore forming bacterium that affects the gastrointestinal (GI) tract. Some people carry the *C-diff* bacterium in their intestines, but never develop symptoms of an infection. The difference between asymptomatic colonization and disease is caused primarily by the production of an enterotoxin (Toxin A) and/or a cytotoxin (Toxin B). The presence of either or both toxins can lead to symptomatic CDI, which is defined as the acute onset of diarrhea with a documented infection with toxigenic *C-diff.* The GI tract contains millions of bacteria, commonly referred to as ''normal flora'' or ''good bacteria,'' which play a role in protecting the body from infection. Antibiotics can kill these good bacteria and allow *C-diff* to multiply and release toxins that damage the cells lining the intestinal wall, resulting in a CDI. CDI is a leading cause of hospital-associated gastrointestinal illnesses. Persons at increased risk for CDI include people who are currently on or who have recently been treated with antibiotics, people who have encountered current or recent hospitalization, people who are older than 65 years, immunocompromised patients, and people who have recently had a diagnosis of CDI. CDI symptoms include, but are not limited to, diarrhea, abdominal pain, and fever. CDI symptoms range in severity from mild (abdominal discomfort, loose stools) to severe (profuse, watery diarrhea, severe abdominal pain, and high fevers). Severe CDI can be life-threatening and, in rare cases, can cause bowel rupture, sepsis and organ failure. CDI is responsible for 14,000 deaths per year in the United States.

C-diff produces two virulent, pro-inflammatory toxins, Toxin A and Toxin B, which target host colonic endothelial cells by binding to endothelial cell surface receptors via combined repetitive oligopeptide (CROP) domains. These toxins cause the release of inflammatory cytokines leading to intestinal fluid secretion and intestinal inflammation. The applicant asserted that ZINPLAVA™ targets Toxin B sites within the CROP domain rather than the *C-diff* organism itself. According to the applicant, by targeting *C-diff* Toxin B, ZINPLAVA™ neutralizes Toxin B, prevents large intestine endothelial cell inflammation, symptoms associated with CDI, and reduces the recurrence of CDI. ZINPLAVA™ received FDA approval on October 21, 2016, as a treatment to reduce the recurrence of CDI in adult patients receiving antibacterial drug treatment for CDI and who are at high risk of CDI recurrence. As previously stated, ZINPLAVA™ is not indicated for the treatment of CDI. ZINPLAVA™ is not an antibacterial drug, and should only be used in conjunction with an antibacterial drug treatment for CDI. ZINPLAVA™ became commercially available on February 10, 2017. Therefore, the newness period for ZINPLAVA™ began on February 10, 2017. The applicant submitted a request for a unique ICD–10–PCS procedure code and was granted approval for the following procedure codes: XW033A3 (Introduction of bezlotoxumab monoclonal antibody, into peripheral vein, percutaneous approach, new technology group 3) and XW043A3 (Introduction of bezlotoxumab monoclonal antibody, into central vein, percutaneous approach, new technology group 3).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for ZINPLAVA™ and consideration of the public comments we received in response to the FY 2018 IPPS/LTCH PPS proposed rule, we approved ZINPLAVA™ for new technology add-on payments for FY 2018 (82 FR 38119). With the new technology add-on payment application, the applicant estimated that the average Medicare beneficiary would require a dosage of 10 mg/kg of ZINPLAVA™ administered as an IV infusion over 60 minutes as a single dose. According to the applicant, the WAC for one dose is $3,800. Under existing § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of ZINPLAVA™ is $1,900 for FY 2019.

With regard to the newness criterion for ZINPLAVA™, we considered the beginning of the newness period to commence on February 10, 2017. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of ZINPLAVA™ onto the U.S. market (February 10, 2020) will occur in the first half of FY 2020, we are proposing to discontinue new technology add-on payments for this technology for FY 2020. We are inviting public comments on our proposal to discontinue new technology add-on payments for ZINPLAVA™ for FY 2020.

d. KYMRIAH® (Tisagenlecleucel) and YESCARTA® (Axicabtagene Ciloleucel)

Two manufacturers, Novartis Pharmaceuticals Corporation and Kite Pharma, Inc., submitted separate applications for new technology add-on payments for FY 2019 for KYMRIAH® (tisagenlecleucel) and YESCARTA® (axicabtagene ciloleucel), respectively. Both of these technologies are CD–19-directed T-cell immunotherapies used for the purposes of treating patients with aggressive variants of non-Hodgkin lymphoma (NHL).

On May 1, 2018, Novartis Pharmaceuticals Corporation received FDA approval for KYMRIAH®'s second indication, the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. On October 18, 2017, Kite Pharma, Inc. received FDA approval for the use of YESCARTA® indicated for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Procedures involving the KYMRIAH® and YESCARTA® therapies are both reported using the following ICD–10–PCS procedure codes: XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3); and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3). In the FY 2019 IPPS/LTCH PPS final rule, we finalized our proposal to assign cases reporting these ICD–10–PCS procedure codes to Pre-MDC MS–DRG 016 for FY 2019 and to revise the title of this MS–DRG to Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy. We refer readers to section II.F.2.d. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a complete discussion of these final policies (83 FR 41172 through 41174).

With respect to the newness criterion, according to both applicants, KYMRIAH® and YESCARTA® are the first CAR T-cell immunotherapies of their kind. As discussed in the FY 2019 IPPS/LTCH PPS proposed and final rules, because potential cases representing patients who may be eligible for treatment using KYMRIAH® and YESCARTA® would group to the same MS–DRGs (because the same ICD–10–CM diagnosis codes and ICD–10–PCS procedures codes are used to report treatment using either KYMRIAH® or YESCARTA®), and we believed that these technologies are intended to treat the same or similar disease in the same or similar patient population, and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action, we believed these two technologies are substantially similar to each other and that it was appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS. For these reasons, we stated that we intended to make one determination regarding approval for new technology add-on payments that would apply to both applications, and in accordance with our policy, would use the earliest market availability date submitted as the beginning of the newness period for both KYMRIAH® and YESCARTA®.

As summarized in the FY 2019 IPPS/LTCH PPS final rule, we received comments from the applicants for KYMRIAH® and YESCARTA® regarding whether KYMRIAH® and YESCARTA® were substantially similar to each other. The applicant for YESCARTA® stated that it believed each technology consists of notable differences in the construction, as well as manufacturing processes and successes that may lead to differences in activity. The applicant encouraged CMS to evaluate YESCARTA® as a separate new technology add-on payment application and approve separate new technology add-on payments for YESCARTA®, effective October 1, 2018, and to not move forward with a single new technology add-on payment evaluation determination that covers both CAR T-cell therapies, YESCARTA® and KYMRIAH®. The applicant for KYMRIAH® indicated that, based on FDA's approval, it agreed with CMS that KYMRIAH® is substantially similar to YESCARTA®, as defined by the new technology add-on payment application evaluation criteria. We refer readers to the FY 2019 IPPS/LTCH PPS final rule for a more detailed summary of these and other public comments we received regarding substantial similarity for KYMRIAH® and YESCARTA®.

After consideration of the public comments we received and for the reasons discussed in the FY 2019 IPPS/LTCH PPS final rule, we stated that we believed that KYMRIAH® and YESCARTA® are substantially similar to one another. We also noted that for FY 2019, there was no payment impact regarding this determination of substantial similarity because the cost of the technologies is the same. However, we stated that we welcomed additional comments in future rulemaking regarding whether KYMRIAH® and YESCARTA® are substantially similar and intended to revisit this issue in the FY 2020 IPPS/LTCH PPS proposed rule. For the reasons discussed in the FY 2019 IPPS/LTCH PPS final rule, we continue to believe that KYMRIAH® and YESCARTA® are substantially similar to each other. We note that for FY 2020, the pricing for KYMRIAH® and YESCARTA® remains the same and, therefore, for FY 2020, there would continue to be no payment impact regarding the determination that the two technologies are substantially similar to each other. Similar to last year, we welcome public comments regarding whether KYMRIAH® and YESCARTA® are substantially similar to each other. We refer readers to the FY 2019 IPPS/LTCH PPS final rule for a complete discussion on newness and substantial similarity regarding KYMRIAH® and YESCARTA®.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for KYMRIAH® and YESCARTA® and consideration of the public comments we received in response to the FY 2019 IPPS/LTCH PPS proposed rule, we approved new technology add-on payments for KYMRIAH® and YESCARTA® for FY 2019 (83 FR 41299). Cases involving KYMRIAH® or YESCARTA® that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW033C3 or XW043C3. The applicants for both KYMRIAH® and YESCARTA® estimated that the average cost for an administered dose of KYMRIAH® or YESCARTA® is $373,000. Under existing § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, for FY 2019, the maximum new technology add-on payment for a case involving the use of KYMRIAH® or YESCARTA® is $186,500.

As stated above, our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. With regard to the newness criterion for KYMRIAH® and YESCARTA®, as discussed in the FY

2019 IPPS/LTCH PPS final rule, according to the applicant for YESCARTA®, the first commercial shipment of YESCARTA® was received by a certified treatment center on November 22, 2017. As stated above, we use the earliest market availability date submitted as the beginning of the newness period for both KYMRIAH® and YESCARTA®. Therefore, we consider the beginning of the newness period for both KYMRIAH® and YESCARTA® to commence November 22, 2017. Because the 3-year anniversary date of the entry of the technology onto the U.S. market (November 22, 2020) will occur after FY 2020, we are proposing to continue new technology add-on payments for KYMRIAH® and YESCARTA® for FY 2020. Under the proposed change to the calculation of the new technology add-on payment amount discussed in section II.H.9. of the preamble of this proposed rule, we are proposing that the maximum new technology add-on payment amount for a case involving the use of KYMRIAH® and YESCARTA® would be increased to $242,450 for FY 2020; that is, 65 percent of the average cost of the technology. However, if we do not finalize the proposed change to the calculation of the new technology add-on payment amount, we are proposing that the maximum new technology add-on payment for a case involving KYMRIAH® or YESCARTA® would remain at $186,500 for FY 2020. We are inviting public comments on our proposals to continue new technology add-on payments for KYMRIAH® and YESCARTA® for FY 2020.

For the reasons discussed in section II.F.2.c. of this proposed rule, we are proposing not to modify the current MS–DRG assignment for cases reporting CAR T-cell therapies for FY 2020. Alternatively, we are seeking public comments on payment alternatives for CAR T-cell therapies. We also are inviting public comments on how these payment alternatives would affect access to care, as well as how they affect incentives to encourage lower drug prices, which is a high priority for this Administration. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41172 through 41174), we are considering approaches and authorities to encourage value-based care and lower drug prices. We are soliciting public comments on how the effective dates of any potential payment methodology alternatives, if any were to be adopted, may intersect and affect future participation in any such alternative approaches. Such payment alternatives could include adjusting the CCRs used to calculate new technology add-on payments for cases involving the use of KYMRIAH® and YESCARTA®. We note that we also considered this payment alternative for FY 2019, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41172 through 41174), and are revisiting this approach given the additional experience with CAR T-cell therapy being provided in hospitals paid under the IPPS and in IPPS-excluded cancer hospitals. We also are requesting public comments on other payment alternatives for these cases, including eliminating the use of CCRs in calculating the new technology add-on payments for cases involving the use of KYMRIAH® and YESCARTA® by making a uniform add-on payment that equals the proposed maximum add-on payment, that is, 65 percent of the cost of the technology (in accordance with the proposed increase in the calculation of the maximum new technology add-on payment amount), which in this instance would be $242,450; and/or using a higher percentage than the proposed 65 percent to calculate the maximum new technology add-on payment amount. If we were to finalize any such changes to the new technology add-on payment for cases involving the use of KYMRIAH® and YESCARTA®, we would also revise our proposed amendments to § 412.88 accordingly.

e. VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection)

Jazz Pharmaceuticals, Inc. submitted an application for new technology add-on payments for the VYXEOS™ technology for FY 2019. VYXEOS™ was approved by FDA on August 3, 2017, for the treatment of adults with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML–MRC).

Treatment of AML diagnoses usually consists of two phases; remission induction and post-remission therapy. Phase one, remission induction, is aimed at eliminating as many myeloblasts as possible. The most common used remission induction regimens for AML diagnoses are the ''7+3'' regimens using an antineoplastic and an anthracycline. Cytarabine and daunorubicin are two commonly used drugs for ''7+3'' remission induction therapy. Cytarabine is continuously administered intravenously over the course of 7 days, while daunorubicin is intermittently administered intravenously for the first 3 days. The ''7+3'' regimen typically achieves a 70 to 80 percent complete remission (CR) rate in most patients under 60 years of age.

VYXEOS™ is a nano-scale liposomal formulation containing a fixed combination of cytarabine and daunorubicin in a 5:1 molar ratio. This formulation was developed by the applicant using a proprietary system known as CombiPlex. According to the applicant, CombiPlex addresses several fundamental shortcomings of conventional combination regimens, specifically the conventional ''7+3'' free drug dosing, as well as the challenges inherent in combination drug development, by identifying the most effective synergistic molar ratio of the drugs being combined in vitro, and fixing this ratio in a nano-scale drug delivery complex to maintain the optimized combination after administration and ensuring exposure of this ratio to the tumor.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for VYXEOS™ and consideration of the public comments we received in response to the FY 2019 IPPS/LTCH PPS proposed rule, we approved VYXEOS™ for new technology add-on payments for FY 2019 (83 FR 41304). Cases involving VYXEOS™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW033B3 (Introduction of cytarabine and caunorubicin liposome antineoplastic into peripheral vein, percutaneous approach, new technology group 3) or XW043B3 (Introduction of cytarabine and daunorubicin liposome antineoplastic into central vein, percutaneous approach, new technology group 3). In its application, the applicant estimated that the average cost of a single vial for VYXEOS™ is $7,750 (daunorubicin 44 mg/m^2 and cytarabine 100 mg/m^2). As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41305), we computed a maximum average of 9.4 vials used in the inpatient hospital setting with the maximum average cost for VYXEOS™ used in the inpatient hospital setting equaling $72,850 ($7,750 cost per vial * 9.4 vials). Under existing § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of VYXEOS™ is $36,425 for FY 2019.

With regard to the newness criterion for VYXEOS™, we consider the beginning of the newness period to commence when VYXEOS™ was approved by the FDA (August 3, 2017). As discussed previously in this section,

in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of the VYXEOS™ onto the U.S. market (August 3, 2020) will occur in the second half of FY 2020, we are proposing to continue new technology add-on payments for this technology for FY 2020. Under the proposed change to the calculation of the new technology add-on payment amount discussed in section II.H.9. of the preamble of this proposed rule, we are proposing that the maximum new technology add-on payment amount for a case involving the use of VYXEOS™ would be $47,353.50 for FY 2020; that is, 65 percent of the average cost of the technology. However, if we do not finalize the proposed change to the calculation of the new technology add-on payment amount, we are proposing that the maximum new technology add-on payment for a case involving VYXEOS™ would remain at $36,425 for FY 2020. We are inviting public comments on our proposals to continue new technology add-on payments for VYXEOS™ for FY 2020.

f. VABOMERE™ (Meropenem-Vaborbactam)

Melinta Therapeutics, Inc., submitted an application for new technology add-on payments for VABOMERE™ for FY 2019. VABOMERE™ is indicated for use in the treatment of adult patients who have been diagnosed with complicated urinary tract infections (cUTIs), including pyelonephritis, caused by designated susceptible bacteria. VABOMERE™ received FDA approval on August 29, 2017.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for VABOMERE™ and consideration of the public comments we received in response to the FY 2019 IPPS/LTCH PPS proposed rule, we approved VABOMERE™ for new technology add-on payments for FY 2019 (83 FR 41311). We noted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41311) that the applicant did not request approval for the use of a unique ICD–10–PCS procedure code for VABOMERE™ for FY 2019 and that as a result, hospitals would be unable to uniquely identify the use of VABOMERE™ on an inpatient claim using the typical coding of an ICD–10–PCS procedure code. We noted that in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53352), with regard to the oral drug DIFICID™, we revised our policy to allow for the use of an alternative code set to identify oral medications where no inpatient procedure is associated for the purposes of new technology add-on payments. We established the use of a NDC as the alternative code set for this purpose and described our rationale for this particular code set. This change was effective for payments for discharges occurring on or after October 1, 2012. In the FY 2019 IPPS/LTCH PPS final rule, we acknowledged that VABOMERE™ is not an oral drug and is administered by IV infusion, but it was the first approved new technology aside from an oral drug with no uniquely assigned inpatient procedure code. Therefore, we believed that the circumstances with respect to the identification of eligible cases using VABOMERE™ are similar to those addressed in the FY 2013 IPPS/LTCH PPS final rule with regard to DIFICID™ because we did not have current ICD–10–PCS code(s) to uniquely identify the use of VABOMERE™ to make the new technology add-on payment. We stated that because we have determined that VABOMERE™ has met all of the new technology add-on payment criteria and cases involving the use of VABOMERE™ would be eligible for such payments for FY 2019, we needed to use an alternative coding method to identify these cases and make the new technology add-on payment for use of VABOMERE™ in FY 2019. Therefore, for the reasons discussed in the FY 2019 IPPS/LTCH PPS final rule and similar to the policy in the FY 2013 IPPS/LTCH PPS final rule, cases involving VABOMERE™ that are eligible for new technology add-on payments for FY 2019 are identified by National Drug Codes (NDC) 65293–0009–01 or 70842–0120–01 (VABOMERE™ Meropenem-Vaborbactam Vial).

According to the applicant, the cost of VABOMERE™ is $165 per vial. A patient receives two vials per dose and three doses per day. Therefore, the per-day cost of VABOMERE™ is $990 per patient. The duration of therapy, consistent with the Prescribing Information, is up to 14 days. Therefore, the estimated cost of VABOMERE™ to the hospital, per patient, is $13,860. We stated in the FY 2019 IPPS/LTCH PPS final rule that based on the limited data from the product's launch, approximately 80 percent of VABOMERE™'s usage would be in the inpatient hospital setting, and approximately 20 percent of VABOMERE™'s usage may take place outside of the inpatient hospital setting. Therefore, the average number of days of VABOMERE™ administration in the inpatient hospital setting is estimated at 80 percent of 14 days, or approximately 11.2 days. As a result, the total inpatient cost for VABOMERE™ is $11,088 ($990 * 11.2 days). Under existing § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of VABOMERE™ is $5,544 for FY 2019.

With regard to the newness criterion for VABOMERE™, we consider the beginning of the newness period to commence when VABOMERE™ received FDA approval (August 29, 2017). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of VABOMERE™ onto the U.S. market (August 29, 2020) will occur during the second half of FY 2020, we are proposing to continue new technology add-on payments for this technology for FY 2020. Under the proposed change to the calculation of the new technology add-on payment amount discussed in section II.H.9. of the preamble of this proposed rule, we are proposing that the maximum new technology add-on payment amount for a case involving the use of VABOMERE™ would be $7,207.20 for FY 2020; that is, 65 percent of the average cost of the technology. However, if we do not finalize the proposed change to the calculation of the new technology add-on payment amount, we are proposing that the maximum new technology add-on payment for a case involving VABOMERE™ would remain at $5,544 for FY 2020.

As noted above, because there was no ICD–10–PCS code(s) to uniquely identify the use of VABOMERE™, we indicated in the FY 2019 IPPS/LTCH PPS final rule that FY 2019 cases involving the use of VABOMERE™ that are eligible for the FY 2019 new technology add-on payments would be identified using an NDC code. Subsequent to the issuance of that final rule, new ICD–10–PCS codes XW033N5 (Introduction of Meropenem-vaborbactam Anti-infective into Peripheral Vein, Percutaneous Approach, New Technology Group 5) and XW043N5 (Introduction of Meropenem-vaborbactam Anti-infective

into Central Vein, Percutaneous Approach, New Technology Group 5) were finalized to identify cases involving the use of VABOMERE™, effective October 1, 2019, as shown in Table 6B—New Procedure Codes, associated with this proposed rule and available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Therefore, for FY 2020, we will use these two ICD–10–PCS codes (XW033N5 and XW043N5) to identify cases involving the use of VABOMERE™ that are eligible for the new technology add-on payments.

While these newly approved ICD–10–PCS procedure codes can be used to uniquely identify cases involving the use of VABOMERE™ for FY 2020, we are concerned that limiting new technology add-on payments only to cases reporting these new ICD–10–PCS codes for FY 2020 could cause confusion because it is possible that some providers may inadvertently continue to bill some claims with the NDC codes rather than the new ICD–10–PCS codes. Therefore, for FY 2020, we are proposing that in addition to using the new ICD–10–PCS codes to identify cases involving the use of VABOMERE™, we would also continue to use the NDC codes to identify cases and make the new technology add-on payments. As a result, we are proposing that cases involving the use of VABOMERE™ that are eligible for new technology add-on payments for FY 2020 would be identified by ICD–10–PCS codes XW033N5 or XW043N5 or NDCs 65293–0009–01 or 70842–0120–01.

We are inviting public comments on our proposal to continue new technology add-on payments for VABOMERE™ for FY 2020 and our proposals for identifying and making new technology add-on payments for cases involving the use of VABOMERE™.

g. remedē® System

Respicardia, Inc. submitted an application for new technology add-on payments for the remedē® System for FY 2019. According to the applicant, the remedē® System is indicated for use as a transvenous phrenic nerve stimulator in the treatment of adult patients who have been diagnosed with moderate to severe central sleep apnea. The remedē® System consists of an implantable pulse generator, and a stimulation and sensing lead. The pulse generator is placed under the skin, in either the right or left side of the chest, and it functions to monitor the patient's respiratory signals. A transvenous lead for unilateral stimulation of the phrenic nerve is placed either in the left pericardiophrenic vein or the right brachiocephalic vein, and a second lead to sense respiration is placed in the azygos vein. Both leads, in combination with the pulse generator, function to sense respiration and, when appropriate, generate an electrical stimulation to the left or right phrenic nerve to restore regular breathing patterns. On October 6, 2017, the remedē® System was approved by the FDA as an implantable phrenic nerve stimulator indicated for the use in the treatment of adult patients who have been diagnosed with moderate to severe CSA. The device was available commercially upon FDA approval. Therefore, the newness period for the remedē® System is considered to begin on October 6, 2017.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the remedē® System and consideration of the public comments we received in response to the FY 2019 IPPS/LTCH PPS proposed rule, we approved the remedē® System for new technology add-on payments for FY 2019. Cases involving the use of the remedē® System that are eligible for new technology add-on payments are identified by ICD–10–PCS procedures codes 0JH60DZ and 05H33MZ in combination with procedure code 05H03MZ (Insertion of neurostimulator lead into right innominate vein, percutaneous approach) or 05H43MZ (Insertion of neurostimulator lead into left innominate vein, percutaneous approach). According to the application, the cost of the remedē® System is $34,500 per patient. Under existing § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of the remedē® System is $17,250 for FY 2019 (83 FR 41320).

With regard to the newness criterion for the remedē® System, we consider the beginning of the newness period to commence when the remedē® System was approved by the FDA on October 6, 2017. Because the 3-year anniversary date of the entry of the remedē® System onto the U.S. market (October 6, 2020) will occur after FY 2020, we are proposing to continue new technology add-on payments for this technology for FY 2020. Under the proposed change to the calculation of the new technology add-on payment amount discussed in section II.H.9. of the preamble of this proposed rule, we are proposing that the maximum new technology add-on payment amount for a case involving the use of the remedē® System would be $22,425 for FY 2020; that is, 65 percent of the average cost of the technology. However, if we do not finalize the proposed change to the calculation of the new technology add-on payment amount, we are proposing that the maximum new technology add-on payment for a case involving the remedē® System would remain at $17,250 for FY 2020. We are inviting public comments on our proposals to continue new technology add-on payments for the remedē® System for FY 2020.

h. ZEMDRI™ (Plazomicin)

Achaogen, Inc. submitted an application for new technology add-on payments for ZEMDRI™ (Plazomicin) for FY 2019. According to the applicant, ZEMDRI™ (Plazomicin) is a next-generation aminoglycoside antibiotic, which has been found in vitro to have enhanced activity against many multi-drug resistant (MDR) gram-negative bacteria. The applicant received approval from the FDA on June 25, 2018, for use in the treatment of adults who have been diagnosed with cUTIs, including pyelonephritis. After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for ZEMDRI™ and consideration of the public comments we received in response to the FY 2019 IPPS/LTCH PPS proposed rule, we approved ZEMDRI™ for new technology add-on payments for FY 2019 (83 FR 41334). Cases involving ZEMDRI™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW033G4 (Introduction of Plazomicin anti-infective into peripheral vein, percutaneous approach, new technology group 4) or XW043G4 (Introduction of Plazomicin anti-infective into central vein, percutaneous approach, new technology group 4). In its application, the applicant estimated that the average Medicare beneficiary would require a dosage of 15 mg/kg administered as an IV infusion as a single dose. According to the applicant, the WAC for one dose is $330, and patients will typically require 3 vials for the course of treatment with ZEMDRI™ per day for an average duration of 5.5 days. Therefore, the total cost of ZEMDRI™ per patient is $5,445. Under existing § 412.88(a)(2), we limit new technology add-on payments to the

lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of ZEMDRI™ is $2,722.50 for FY 2019. With regard to the newness criterion for ZEMDRI™, we consider the beginning of the newness period to commence when ZEMDRI™ was approved by the FDA on June 25, 2018. Because the 3-year anniversary date of the entry of ZEMDRI™ onto the U.S. market (June 25, 2021) will occur after FY 2020, we are proposing to continue new technology add-on payments for this technology for FY 2020. Under the proposed change to the calculation of the new technology add-on payment amount discussed in section II.H.9. of the preamble of this proposed rule, we are proposing that the maximum new technology add-on payment amount for a case involving the use of ZEMDRI™ would be $3,539.25 for FY 2020; that is, 65 percent of the average cost of the technology. However, if we do not finalize the proposed change to the calculation of the new technology add-on payment amount, we are proposing that the maximum new technology add-on payment for a case involving ZEMDRI™ would remain at $2,722.50 for FY 2020. We are inviting public comments on our proposals to continue new technology add-on payments for ZEMDRI™ for FY 2020.

i. GIAPREZA™

The La Jolla Pharmaceutical Company submitted an application for new technology add-on payments for GIAPREZA™ for FY 2019. GIAPREZA™, a synthetic human angiotensin II, is administered through intravenous infusion to raise blood pressure in adult patients who have been diagnosed with septic or other distributive shock.

GIAPREZA™ was granted a Priority Review designation under FDA's expedited program and received FDA approval on December 21, 2017, for the use in the treatment of adults who have been diagnosed with septic or other distributive shock as an intravenous infusion to increase blood pressure. After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for GIAPREZA™ and consideration of the public comments we received in response to the FY 2019 IPPS/LTCH PPS proposed rule, we approved GIAPREZA™ for new technology add-on payments for FY 2019 (83 FR 41342). Cases involving GIAPREZA™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW033H4 (Introduction of synthetic human angiotensin II into peripheral vein, percutaneous approach, new technology, group 4) or XW043H4 (Introduction of synthetic human angiotensin II into central vein, percutaneous approach, new technology group 4). In its application, the applicant estimated that the average Medicare beneficiary would require a dosage of 20 ng/kg/min administered as an IV infusion over 48 hours, which would require 2 vials. The applicant explained that the WAC for one vial is $1,500, with each episode-of-care costing $3,000 per patient. Under existing § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of GIAPREZA™ is $1,500 for FY 2019.

With regard to the newness criterion for GIAPREZA™, we consider the beginning of the newness period to commence when GIAPREZA™ was approved by the FDA (December 21, 2017). Because the 3-year anniversary date of the entry of GIAPREZA™ onto the U.S. market (December 21, 2020) would occur after FY 2020, we are proposing to continue new technology add-on payments for this technology for FY 2020. Under the proposed change to the calculation of the new technology add-on payment discussed in section II.H.9. of the preamble of this proposed rule, we are proposing that the maximum new technology add-on payment amount for a case involving the use of GIAPREZA™ would be $1,950 for FY 2020; that is, 65 percent of the average cost of the technology. However, if we do not finalize the proposed change to the calculation of the new technology add-on payment amount, we are proposing that the maximum new technology add-on payment for a case involving GIAPREZA™ would remain at $1,500 for FY 2020. We are inviting public comments on our proposals to continue new technology add-on payments for GIAPREZA™ for FY 2020.

j. Cerebral Protection System (Sentinel® Cerebral Protection System)

Claret Medical, Inc. submitted an application for new technology add-on payments for the Cerebral Protection System (Sentinel® Cerebral Protection System) for FY 2019. According to the applicant, the Sentinel Cerebral Protection System is indicated for the use as an embolic protection (EP) device to capture and remove thrombus and debris while performing transcatheter aortic valve replacement (TAVR) procedures. The device is percutaneously delivered via the right radial artery and is removed upon completion of the TAVR procedure. The De Novo request for the Sentinel® Cerebral Protection System was granted by FDA on June 1, 2017 (DEN160043).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the Sentinel® Cerebral Protection System and consideration of the public comments we received in response to the FY 2019 IPPS/LTCH PPS proposed rule, we approved the Sentinel® Cerebral Protection System for new technology add-on payments for FY 2019 (83 FR 41348). Cases involving the Sentinel® Cerebral Protection System that are eligible for new technology add-on payments are identified by ICD–10–PCS code X2A5312 (Cerebral embolic filtration, dual filter in innominate artery and left common carotid artery, percutaneous approach). In its application, the applicant estimated that the cost of the Sentinel® Cerebral Protection System is $2,800. Under existing § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of the Sentinel® Cerebral Protection System is $1,400 for FY 2019.

With regard to the newness criterion for the Sentinel® Cerebral Protection System, we consider the beginning of the newness period to commence when the FDA granted the De Novo request for the Sentinel® Cerebral Protection System (June 1, 2017). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of the Sentinel® Cerebral Protection System onto the U.S. market (June 1, 2020) will occur in the second half of FY 2020, we are proposing to continue new technology add-on payments for this technology for FY 2020. Under the proposed change to the calculation of the new technology add-on payment amount discussed in section II.H.9. of the preamble of this proposed rule, we are proposing that the maximum new technology add-on payment amount for

a case involving the use of the Sentinel® Cerebral Protection System would be $1,820 for FY 2020; that is, 65 percent of the average cost of the technology. However, if we do not finalize the proposed change to the calculation of the new technology add-on payment amount, we are proposing that the maximum new technology add-on payment for a case involving the Sentinel® Cerebral Protection System would remain at $1,400 for FY 2020. We are inviting public comments on our proposals to continue new technology add-on payments for the Sentinel® Cerebral Protection System for FY 2020.

k. The AQUABEAM System (Aquablation)

PROCEPT BioRobotics Corporation submitted an application for new technology add-on payments for the AQUABEAM System (Aquablation) for FY 2019. According to the applicant, the AQUABEAM System is indicated for the use in the treatment of patients experiencing lower urinary tract symptoms caused by a diagnosis of benign prostatic hyperplasia (BPH). The AQUABEAM System consists of three main components: A console with two high-pressure pumps, a conformal surgical planning unit with trans-rectal ultrasound imaging, and a single-use robotic hand-piece. The applicant reported that the AQUABEAM System provides the operating surgeon a multi-dimensional view, using both ultrasound image guidance and endoscopic visualization, to clearly identify the prostatic adenoma and plan the surgical resection area. Based on the planning inputs from the surgeon, the system's robot delivers Aquablation, an autonomous waterjet ablation therapy that enables targeted, controlled, heat-free and immediate removal of prostate tissue used for the purpose of treating lower urinary tract symptoms caused by a diagnosis of BPH. The combination of surgical mapping and robotically-controlled resection of the prostate is designed to offer predictable and reproducible outcomes, independent of prostate size, prostate shape or surgeon experience.

The FDA granted the AQUABEAM System's De Novo request on December 21, 2017, for use in the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia. The applicant stated that the AQUABEAM System was made available on the U.S. market immediately after the FDA granted the De Novo request.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the AQUABEAM System and consideration of the public comments we received in response to the FY 2019 IPPS/LTCH PPS proposed rule, we approved the AQUABEAM System for new technology add-on payments for FY 2019 (83 FR 41355). Cases involving the AQUABEAM System that are eligible for new technology add-on payments are identified by ICD–10–PCS code XV508A4 (Destruction of prostate using robotic waterjet ablation, via natural or artificial opening endoscopic, new technology group 4). The applicant estimated that the average Medicare beneficiary would require the transurethral procedure of one AQUABEAM System per patient. According to the application, the cost of the AQUABEAM System is $2,500 per procedure. Under existing § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of the AQUABEAM System's Aquablation System is $1,250 for FY 2019.

With regard to the newness criterion for the AQUABEAM System, we consider the beginning of the newness period to commence on the date the FDA granted the De Novo request (December 21, 2017). As noted above and in the FY 2019 rulemaking, the applicant stated that the AQUABEAM System was made available on the U.S. market immediately after the FDA granted the De Novo request.

We note that in the FY 2019 IPPS/LTCH PPS final rule, we inadvertently misstated the newness period beginning date as April 19, 2018 (83 FR 41351). As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41350), in its public comment in response to the FY 2019 IPPS/LTCH PPS proposed rule, the applicant explained that, while the AQUABEAM System received approval from the FDA for its De Novo request on December 21, 2017, local non-coverage determinations in the Medicare population resulted in the first case being delayed until April 19, 2018. Therefore, the applicant believed that the newness period should begin on April 19, 2018, instead of the date FDA granted the De Novo request. In the final rule, we responded that with regard to the beginning of the technology's newness period, as discussed in the FY 2005 IPPS final rule (69 FR 49003), the timeframe that a new technology can be eligible to receive new technology add-on payments begins when data begin to become available. While local non-coverage determinations may limit the use of a technology in different regions in the country, a technology may be available in regions where no local non-coverage decision existed (with data beginning to become available). We also explained that under our historical policy we do not consider how frequently the medical service or technology has been used in the Medicare population in our determination of newness (as discussed in the FY 2006 IPPS final rule (70 FR 47349)). Consistent with this response, and as indicated in the proposed rule and elsewhere in the final rule, we believe the beginning of the newness period to commence on the first day the AQUABEAM System was commercially available (December 21, 2017). As noted, the later statement that the newness period beginning date for the AQUABEAM System is April 19, 2018 was an inadvertent error. As we indicated in the FY 2019 IPPS/LTCH PPS final rule, we welcome further information from the applicant for consideration regarding the beginning of the newness period.

Because the 3-year anniversary date of the entry of the AQUABEAM System onto the U.S. market (December 21, 2020) will occur after FY 2020, we are proposing to continue new technology add-on payments for this technology for FY 2020. Under the proposed change to the calculation of the new technology add on payment amount discussed in section II.H.9. of the preamble of this proposed rule, we are proposing that the maximum new technology add-on payment amount for a case involving the use of the AQUABEAM System would be $1,625 for FY 2020; that is, 65 percent of the average cost of the technology. However, if we do not finalize the proposed change to the calculation of the new technology add-on payment amount, we are proposing that the maximum new technology add-on payment for a case involving the AQUABEAM System would remain at $1,250 for FY 2020. We are inviting public comments on our proposals to continue new technology add-on payments for the AQUABEAM System for FY 2020.

l. AndexXa™ (Andexanet alfa)

Portola Pharmaceuticals, Inc. (Portola) submitted an application for new technology add-on payments for FY 2019 for the use of AndexXa™ (Andexanet alfa).

AndexXa™ received FDA approval on May 3, 2018, and is indicated for use in the treatment of patients who are

receiving treatment with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for AndexXa™ and consideration of the public comments we received in response to the FY 2019 IPPS/LTCH PPS proposed rule, we approved AndexXa™ for new technology add-on payments for FY 2019 (83 FR 41362). Cases involving the use of AndexXa™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW03372 (Introduction of Andexanet alfa, Factor Xa inhibitor reversal agent into peripheral vein, percutaneous approach, new technology group 2) or XW04372 (Introduction of Andexanet alfa, Factor Xa inhibitor reversal agent into central vein, percutaneous approach, new technology group 2). The applicant explained that the WAC for 1 vial is $2,750, with the use of an average of 10 vials for the low dose and 18 vials for the high dose. The applicant noted that per the clinical trial data, 90 percent of cases were administered a low dose and 10 percent of cases were administered the high dose. The weighted average between the low and high dose is an average of 10.22727 vials. Therefore, the cost of a standard dosage of AndexXa™ is $28,125 ($2,750 x 10.22727). Under existing § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of AndexXa™ is $14,062.50 for FY 2019.

With regard to the newness criterion for AndexXa™, we consider the beginning of the newness period to commence when AndexXa™ received FDA approval (May 3, 2018). Because the 3-year anniversary date of the entry of AndexXa™ onto the U.S. market (May 3, 2021) will occur after FY 2020, we are proposing to continue new technology add-on payments for this technology for FY 2020. Under the proposed change to the calculation of the new technology add-on payment amount discussed in section II.H.9. of the preamble of this proposed rule, we are proposing that the maximum new technology add-on payment amount for a case involving the use of AndexXa™ would be $18,281.25 for FY 2020; that is, 65 percent of the average cost of the technology. However, if we do not finalize the proposed change to the calculation of the new technology add-on payment amount, we are proposing that the maximum new technology add-on payment for a case involving AndexXa™ would remain at $14,062.50 for FY 2020. We are inviting public comments on our proposals to continue new technology add-on payments for AndexXa™ for FY 2020.

5. Proposed FY 2020 Applications for New Technology Add-On Payments

We received 18 applications for new technology add-on payments for FY 2020. In accordance with the regulations under § 412.87(c), applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. One applicant withdrew its application prior to the issuance of this proposed rule. A discussion of the 17 remaining applications is presented below.

a. AZEDRA® (Ultratrace® iobenguane Iodine-131) Solution

Progenics Pharmaceuticals, Inc. submitted an application for new technology add-on payments for AZEDRA® (Ultratrace® iobenguane Iodine-131) for FY 2020. (We note that Progenics Pharmaceuticals, Inc. previously submitted an application for new technology add-on payments for AZEDRA® for FY 2019, which was withdrawn prior to the issuance of the FY 2019 IPPS/LTCH PPS final rule.) AZEDRA® is a drug solution formulated for intravenous (IV) use in the treatment of patients who have been diagnosed with obenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma. AZEDRA® contains a small molecule ligand consisting of meta-iodobenzylguanidine (MIBG) and ^{131}Iodine (^{131}I) (hereafter referred to as ''^{131}I–MIBG''). The applicant noted that iobenguane Iodine-131 is also known as ^{131}I–MIBG.

The applicant reported that pheochromocytomas and paragangliomas are rare tumors with an incidence of approximately 2 to 8 people per million per year.[1] [2] Both tumors are catecholamine-secreting neuroendocrine tumors, with pheochromocytomas being the more common of the two and comprising 80 to 85 percent of cases. While 10 percent of pheochromocytomas are malignant, whereby ''malignant'' is defined by the World Health Organization (WHO) as ''the presence of distant metastases,'' paragangliomas have a malignancy frequency of 25 percent.[3] [4] Approximately one-half of malignant tumors are pronounced at diagnosis, while other malignant tumors develop slowly within 5 years.[5] Pheochromocytomas and paragangliomas tend to be indistinguishable at the cellular level and frequently at the clinical level. For example catecholamine-secreting paragangliomas often present clinically like pheochromocytomas with hypertension, episodic headache, sweating, tremor, and forceful palpitations.[6] Although pheochromocytomas and paragangliomas can share overlapping histopathology, epidemiology, and molecular pathobiology characteristics, there are differences between these two neuroendocrine tumors in clinical behavior, aggressiveness and metastatic potential, biochemical findings and association with inherited genetic syndrome differences, highlighting the importance of distinguishing between the presence of malignant pheochromocytoma and the presence of malignant paraganglioma. At this time, there is no curative treatment for malignant pheochromocytomas and paragangliomas. Successful management of these malignancies requires a multidisciplinary approach of decreasing tumor burden, controlling endocrine activity, and treating debilitating symptoms. According to the applicant, decreasing metastatic tumor burden would address the leading cause of mortality in this patient population, where the 5-year survival rate is 50 percent for patients with untreated malignant pheochromocytomas and paragangliomas.[7] The applicant stated that controlling catecholamine

[1] Beard, C.M., Sheps, S.G., Kurland, L.T., Carney, J.A., Lie, J.T., ''Occurrence of pheochromocytoma in Rochester, Minnesota'', pp. 1950–1979.

[2] Stenström, G., Svärdsudd, K., ''Pheochromocytoma in Sweden 1958–1981. An analysis of the National Cancer Registry Data,'' *Acta Medica Scandinavica,* 1986, vol. 220(3), pp. 225–232.

[3] Fishbein, Lauren, ''Pheochromocytoma and Paraganglioma,'' *Hematology/Oncology Clinics* 30, no. 1, 2016, pp. 135–150.

[4] Lloyd, R.V., Osamura, R.Y., Klöppel, G., & Rosai, J. (2017). World Health Organization (WHO) Classification of Tumours of Endocrine Organs. Lyon, France: International Agency for Research on Center (IARC).

[5] Kantorovich, Vitaly, and Karel Pacak. ''Pheochromocytoma and paraganglioma.'' *Progress in Brain Research.,* 2010, vol. 182, pp. 343–373.

[6] Carty, SE, Young, W.F., Elfky, A., ''Paraganglioma and pheochromocytoma: Management of malignant disease,'' *UpToDate.* Available at: *https://www.uptodate.com/contents/paraganglioma-and-pheochromocytoma-management-of-malignant-disease.*

[7] Kantorovich, Vitaly, and Karel Pacak. ''Pheochromocytoma and paraganglioma.'' *Progress in Brain Research.,* 2010, vol. 182, pp. 343–373.

hypersecretion (for example, severe paroxysmal or sustained hypertension, palpitations and arrhythmias) would also mean decreasing morbidity associated with hypertension (for example, risk of stroke, myocardial infarction and renal failure), and begin to address the 30-percent cardiovascular mortality rate associated with malignant pheochromocytomas and paragangliomas.

The applicant reported that, prior to the introduction of AZEDRA®, controlling catecholamine activity in pheochromocytomas and paragangliomas was medically achieved with administration of combined alpha and beta-adrenergic blockade, and surgically with tumor tissue reduction. Because there is no curative treatment for malignant pheochromocytomas and paragangliomas, resecting both primary and metastatic lesions whenever possible to decrease tumor burden [8] provides a methodology for controlling catecholamine activity and lowering cardiovascular mortality risk. Besides surgical removal of tumor tissue for lowering tumor burden, there are other treatment options that depend upon tumor type (that is, pheochromocytoma tumors versus paraganglioma tumors), anatomic location, and the number and size of the metastatic tumors. These treatment options include: (1) Radiation therapy; (2) nonsurgical local ablative therapy with radiofrequency ablation, cryoablation, and percutaneous ethanol injection; (3) transarterial chemoembolization for liver metastases; and (4) radionuclide therapy using metaiodobenzylguanidine (MIBG) or somatostatin. Regardless of the method to reduce local tumor burden, periprocedural medical care is needed to prevent massive catecholamine secretion and hypertensive crisis.[9]

The applicant stated that AZEDRA® specifically targets neuroendocrine tumors arising from chromaffin cells of the adrenal medulla (in the case of pheochromocytomas) and from neuroendocrine cells of the extra-adrenal autonomic paraganglia (in the case of paragangliomas).[10] According to the applicant, AZEDRA® is a more consistent form of ^{131}I–MIBG compared to compounded formulations of ^{131}I–MIBG that are not approved by the FDA. AZEDRA® (iobenguane I 131) (AZEDRA) was approved by the FDA on July 30, 2018, and according to the applicant, is the first and only drug indicated for the treatment of adult and pediatric patients 12 years and older who have been diagnosed with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. Among local tumor tissue reduction options, use of external beam radiation therapy (EBRT) at doses greater than 40 Gy can provide local pheochromocytoma and paraganglioma tumor control and relief of symptoms for tumors at a variety of sites, including the soft tissues of the skull base and neck, abdomen, and thorax, as well as painful bone metastases.[11] However, the applicant stated that EBRT irradiated tissues are unresponsive to subsequent treatment with ^{131}I–MIBG radionuclide.[12] MIBG was initially used for the imaging of paragangliomas and pheochromocytomas because of its similarity to noradrenaline, which is taken up by chromaffin cells. Conventional MIBG used in imaging expanded to off-label use in patients who had been diagnosed with malignant pheochromocytomas and paragangliomas. Because ^{131}I–MIBG is sequestered within pheochromocytoma and paraganglioma tumors, subsequent malignant cell death occurs from radioactivity. Approximately 50 percent of tumors are eligible for treatment involving ^{131}I–MIBG therapy based on having MIBG uptake with diagnostic imaging. According to the applicant, despite uptake by tumors, studies have also found that ^{131}I–MIBG therapy has been limited by total radiation dose, hematologic side effects, and hypertension. While the pathophysiology of total radiation dose and hematologic side effects are more readily understandable, hypertension is believed to be precipitated by large quantities of non-iodinated MIBG or ''cold'' MIBG being introduced along with radioactive ^{131}I–MIBG therapy.[13] The ''cold'' MIBG blocks synaptic reuptake of norepinephrine, which can lead to tachycardia and paroxysmal hypertension within the first 24 hours, the majority of which occur within 30 minutes of administration and can be dose-limiting.[14]

The applicant asserted that its new proprietary manufacturing process called Ultratrace® allows AZEDRA® to be manufactured without the inclusion of unlabeled or ''cold'' MIBG in the final formulation. The applicant also noted that targeted radionuclide MIBG therapy to reduce tumor burden is one of two treatments that have been studied the most. The other treatment is cytotoxic chemotherapy and, specifically, Carboplatin, Vincristine, and Dacarbazine (CVD). The applicant stated that cytotoxic chemotherapy is an option for patients who experience symptoms with rapidly progressive, non-resectable, high tumor burden, and that cytotoxic chemotherapy is another option for a large number of metastatic bone lesions.[15] According to the applicant, CVD was believed to have an effect on malignant pheochromocytomas and paragangliomas due to the embryonic origin being similar to neuroblastomas. The response rates to CVD have been variable between 25 percent and 50 percent.[16] [17] These patients experience side effects consistent with chemotherapeutic treatment with CVD, with the added concern of the precipitation of hormonal complications such as hypertensive crisis, thereby requiring close monitoring during cytotoxic chemotherapy.[18] According to the applicant, use of CVD relative to other tumor burden reduction options is not

[8] Noda, T., Nagano, H., Miyamoto, A., et al., ''Successful outcome after resection of liver metastasis arising from an extraadrenal retroperitoneal paraganglioma that appeared 9 years after surgical excision of the primary lesion,'' *Int J Clin Oncol,* 2009, vol. 14, pp. 473.

[9] Carty, SE, Young, W.F., Elfky, A., ''Paraganglioma and pheochromocytoma: Management of malignant disease,'' *UpToDate.* Available at: *https://www.uptodate.com/contents/paraganglioma-and-pheochromocytoma-management-of-malignant-disease.*

[10] Ibid.

[11] Ibid.

[12] Fitzgerald, P.A., Goldsby, R.E., Huberty, J.P., et al., ''Malignant pheochromocytomas and paragangliomas: a phase II study of therapy with high-dose 131I-metaiodobenzylguanidine (131I–MIBG),'' *Ann N Y Acad Sci,* 2006, vol. 1073, pp. 465.

[13] Loh, K.C., Fitzgerald, P.A., Matthay, K.K., Yeo, P.P., Price, DC, ''The treatment of malignant pheochromocytoma with iodine-131 metaiodobenzylguanidine (^{131}I–MIBG): a comprehensive review of 116 reported patients,'' *J Endocrinol Invest,* 1997, vol. 20(11), pp. 648–658.

[14] Gonias, S, et al., ''Phase II Study of High-Dose [^{131}I]Metaiodobenzylguanidine Therapy for Patients With Metastatic Pheochromocytoma and Paraganglioma,'' *J of Clin Onc,* July 27, 2009.

[15] Carty, SE, Young, W.F., Elfky, A., ''Paraganglioma and pheochromocytoma: Management of malignant disease,'' *UpToDate.* Available at: *https://www.uptodate.com/contents/paraganglioma-and-pheochromocytoma-management-of-malignant-disease.*

[16] Niemeijer, N.D., Alblas, G., Hulsteijn, L.T., Dekkers, O.M. and Corssmit, E.P. M., ''Chemotherapy with cyclophosphamide, vincristine and dacarbazine for malignant paraganglioma and pheochromocytoma: systematic review and meta-analysis,'' *Clinical endocrinology,* 2014, vol 81(5), pp. 642–651.

[17] Ayala-Ramirez, Montserrat, et al., ''Clinical Benefits of Systemic Chemotherapy for Patients with Metastatic Pheochromocytomas or Sympathetic Extra-Adrenal Paragangliomas: Insights from the Largest Single Institutional Experience,'' *Cancer,* 2012, vol. 118(11), pp. 2804–2812.

[18] Wu, L.T., Dicpinigaitis, P., Bruckner, H., et al., ''Hypertensive crises induced by treatment of malignant pheochromocytoma with a combination of cyclophosphamide, vincristine, and dacarbazine,'' *Med Pediatr Oncol,* 1994, vol. 22(6), pp. 389–392.

an ideal treatment because of nearly 100 percent recurrence rates, and the need for chemotherapy cycles to be continually readministered at the risk of increased systemic toxicities and eventual development of resistance. Finally, there is a subgroup of patients that are asymptomatic and have slower progressing tumors where frequent follow-up is an option for care.[19] Therefore, the applicant believed that AZEDRA® offers cytotoxic radioactive therapy for the indicated population that avoids harmful side effects that typically result from use of low-specific activity products.

The applicant reported that the recommended AZEDRA® dosage and frequency for patients receiving treatment involving ^{131}I–MIBG therapy for a diagnosis of avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma tumors is:

- Dosimetric Dosing—5 to 6 micro curies (mCi) (185 to 222 MBq) for a patient weighing more than or equal to 50 kg, and 0.1 mCi/kg (3.7 MBq/kg) for patients weighing less than 50 kg. Each recommended dosimetric dose is administered as an IV injection.
- Therapeutic Dosing—500 mCi (18.5 GBq) for patients weighing more than 62.5 kg, and 8 mCi/kg (296 MBq/kg) for patients weighing less than or equal to 62.5 kg. Therapeutic doses are administered by IV infusion, in ~50 mL over a period of ~30 minutes (100 mL/hour), administered approximately 90 days apart.

With respect to the newness criterion, the applicant indicated that FDA granted Orphan Drug designation for AZEDRA® on January 18, 2006, followed by Fast Track designation on March 8, 2006, and Breakthrough Therapy designation on July 26, 2015. The applicant's New Drug Application (NDA) proceeded on a rolling basis, and was completed on November 2, 2017. AZEDRA® was approved by the FDA on July 30, 2018, for the treatment of adult and pediatric patients 12 years and older who have been diagnosed with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy through a New Drug Approval (NDA) filed under Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act and 21 CFR 314.50. Currently, there are no approved ICD–10–PCS procedure codes to uniquely identify procedures involving the administration of AZEDRA®. We note that the applicant submitted a request for approval for a unique ICD–10–PCS code for the administration of AZEDRA® beginning in FY 2020.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action, the applicant stated that while AZEDRA® and low-specific activity conventional I–131 MIBG both target the same transporter sites on the tumor cell surface, the therapies' safety and efficacy outcomes are different. These differences in outcomes are because AZEDRA® is manufactured using the proprietary Ultratrace® technology, which maximizes the molecules that carry the tumoricidal component (I–131 MIBG) and minimizes the extraneous unlabeled component (MIBG, free ligands), which could cause cardiovascular side effects. Therefore, according to the applicant, AZEDRA® is designed to increase efficacy and decrease safety risks, whereas conventional I–131 MIBG uses existing technologies and results in a product that overwhelms the normal reuptake system with excess free ligands, which leads to safety issues as well as decreasing the probability of the ^{131}I–MIBG binding to the tumor cells.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant noted that there are no specific MS–DRGs for the assignment of cases involving the treatment of patients who have been diagnosed with pheochromocytoma and paraganglioma. We believe that potential cases representing patients who may be eligible for treatment involving the administration of AZEDRA® would be assigned to the same MS–DRGs as cases representing patients who receive treatment for a diagnosis of iobenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma. We also refer readers to the cost criterion discussion below, which includes the applicant's list of the MS–DRGs to which potential cases involving treatment with the administration of AZEDRA® most likely would map.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, AZEDRA® is the only FDA-approved drug indicated for use in the treatment of patients who have been diagnosed with malignant pheochromocytoma and paraganglioma tumors that avidly take up ^{131}I–MIBG and are recurrent and/or unresectable. The applicant stated that these patients face serious mortality and morbidity risks if left untreated, as well as potentially suffer from side effects if treated by available off-label therapies.

The applicant also contended that AZEDRA® can be distinguished from other currently available treatments because it potentially provides the following advantages:

- AZEDRA® will have a very limited impact on normal norepinephrine reuptake due to the negligible amount of unlabeled MIBG present in the dose. Therefore, AZEDRA® is expected to pose a much lower risk of acute drug-induced hypertension.
- There is minimal unlabeled MIBG to compete for the norepinephrine transporter binding sites in the tumor, resulting in more effective delivery of radioactivity.
- Current off-label therapeutic use of ^{131}I is compounded by individual pharmacies with varied quality and conformance standards.
- Because of its higher specific activity (the activity of a given radioisotope per unit mass), AZEDRA® infusion times are significantly shorter than conventional ^{131}I administrations.

Therefore, with these potential advantages, the applicant maintained that AZEDRA® represents an option for the treatment of patients who have been diagnosed with malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma tumors, where there is a clear, unmet medical need.

For the reasons cited earlier, the applicant believed that AZEDRA® is not substantially similar to other currently available therapies and/or technologies and meets the ''newness'' criterion. We are inviting public comments on whether AZEDRA® is substantially similar to other currently available therapies and/or technologies and meets the ''newness'' criterion.

With regard to the cost criterion, the applicant conducted an analysis using FY 2015 MedPAR data to demonstrate that AZEDRA® meets the cost criterion.

The applicant searched for potential cases representing patients who may be eligible for treatment involving AZEDRA® that had one of the following ICD–9–CM diagnosis codes (which the applicant believed is indicative of

[19] Carty, SE, Young, W.F., Elfky, A., ''Paraganglioma and pheochromocytoma: Management of malignant disease,'' *UpToDate.* Available at: *https://www.uptodate.com/contents/paraganglioma-and-pheochromocytoma-management-of-malignant-disease.*

diagnosis appropriate for treatment involving AZEDRA®): 194.0 (Malignant neoplasm of adrenal gland), 194.6 (Malignant neoplasm of aortic body and other paraganglia), 209.29 (Malignant carcinoid tumor of other sites), 209.30 (Malignant poorly differentiated neuroendocrine carcinoma, any site), 227.0 (Benign neoplasm of adrenal gland), 237.3 (Neoplasm of uncertain behavior of paraganglia)—in combination with one of the following ICD–9–CM procedure codes describing the administration of a radiopharmaceutical: 00.15 (High-dose infusion interleukin-2); 92.20 (Infusion of liquid brachytherapy radioisotope); 92.23 (Radioisotopic teleradiotherapy); 92.27 (Implantation or insertion of radioactive elements); 92.28 (Injection or instillation of radioisotopes). The applicant reported that the potential cases used for this analysis mapped to MS–DRGs 054 and 055 (Nervous System Neoplasms with and without MCC, respectively), MS–DRG 271 (Other Major Cardiovascular Procedures with CC), MS–DRG 436 (Malignancy of Hepatobiliary System or Pancreas with CC), MS–DRG 827 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with CC), and MS–DRG 843 (Other Myeloproliferative Disorders or Poorly Differentiated Neoplastic Diagnosis with MCC). Due to patient privacy concerns, because the number of cases under each MS–DRG was less than 11 in total, the applicant assumed an equal distribution between these 6 MS–DRGs. Based on the FY 2019 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case-weighted threshold amount was $60,136. Using the identified cases, the applicant determined that the average unstandardized charge per case ranged from $21,958 to $152,238 for the 6 evaluated MS–DRGs. After removing charges estimated to be associated with precursor agents, the applicant used a 3-year inflation factor of 1.1436 (a yearly inflation factor of 1.04574 applied over 3 years), based on the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527), to inflate the charges from FY 2015 to FY 2018. The applicant provided an estimated average of $151,000 per therapeutic dose per patient, based on the wholesale acquisition cost of the drug and the average dosage amount for most patients, with a total cost per patient estimated to be approximately $980,000. After including the cost of the technology, the applicant determined an inflated average case-weighted standardized charge per case of $1,078,631.

We are concerned with the limited number of cases the applicant analyzed. However, we acknowledge the difficulty in obtaining cost data for such a rare condition. We are inviting public comments on whether the AZEDRA® technology meets the cost criterion.

With regard to substantial clinical improvement, the applicant maintained that the use of AZEDRA® has been shown to reduce the incidence of hypertensive episodes and use of antihypertensive medications, reduce tumor size, improve blood pressure control, and reduce secretion of tumor biomarkers. In addition, the applicant asserted that AZEDRA® provides a treatment option for those outlined in its indication patient population. The applicant asserted that AZEDRA® meets the substantial clinical improvement criterion based on the results from two clinical studies: (1) MIP–IB12 (IB12): A Phase I Study of Iobenguane (MIBG) I–131 in Patients With Malignant Pheochromocytoma/Paraganglioma; [20] and (2) MIP–IB12B (IB12B): A Study Evaluating Ultratrace® Iobenguane I–131 in Patients With Malignant Relapsed/Refractory Pheochromocytoma/Paraganglioma. The applicant explained that the IB12B study is similar to the IB12 study in that both studies evaluated two open-label, single-arm studies. The applicant reported that both studies included patients who had been diagnosed with malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma tumors, and both studies assessed objective tumor response, biochemical tumor response, overall survival rates, occurrence of hypertensive crisis, and the long-term benefit of AZEDRA® treatment relative to the need for antihypertensives. However, according to the applicant, the study designs differed in dose regimens (1 dose administered to patients in the IB12 study, and 2 doses administered to patients in the IB12B study) and primary study endpoints. Differences in the designs of the studies prevented direct comparison of study endpoints and pooling of the data. In addition, the applicant stated that results from safety data from the IB12 study and the IB12B study were pooled and used to support substantial clinical improvement assertions. We note that neither the IB12 study nor the IB12B study compared the effects of the use of AZEDRA® to any of the other treatment options to decrease tumor burden (for example, cytotoxic chemotherapy, radiation therapy, and surgical debulking).

Regarding the data results from the IB12 study, the applicant asserted that, based on the reported safety and tolerability, and primary endpoint of radiological response at 12 months, high-specific-activity I–131 MIBG may be an effective alternative therapeutic option for patients who have been diagnosed with iobenguane-avid, metastatic and/or recurrent pheochromocytoma and paraganglioma tumors for whom there are no other approved therapies and for those patients who have failed available treatment options. In addition, the applicant used the exploratory finding of decreased or discontinuation of anti-hypertensive medications relative to baseline medications as evidence that AZEDRA® has clinical benefit and positive impact on the long-term effects of hypertension induced norepinephrine producing malignant pheochromocytoma and paraganglioma tumors. We understand that the applicant used antihypertensive medications as a proxy to assess the long-term effects of hypertension such as renal, myocardial, and cerebral end organ damage. The applicant reported that it studied 15 of the original IB12 study's 21-patient cohort, and found 33 percent (n=5) had decreased or discontinuation of antihypertensive medications during the 12 months of follow-up. However, the applicant did not provide additional data on the incidence of renal insufficiency/failure, myocardial ischemic/infarction events, or transient ischemic attacks or strokes. Therefore, it is unclear to us if these five patients also had decreased urine metanephrines, changed their diet, lost significant weight, or if other underlying comorbidities that influence hypertension were resolved, making it difficult to understand the significance of this exploratory finding.

Regarding the applicant's assertion that the use of AZEDRA® is safer and more effective than alternative therapies, we note that the IB12 study was a dose-escalating study and did not compare current therapies with the use of AZEDRA®. We also note the following: (1) The average age of the 21 enrolled patients in the IB12 study was 50.4 years old (a range of 30 to 72 years old); (2) the gender distribution was 61.9 percent (n=13) male and 38.1 percent (n=8) female; and (3) 76.2 percent (n=16) were white, 14.3 percent (n=3) were black or African American, and 9.5 percent (n=2) were Asian. We

[20] Noto, Richard B., et. al., ''Phase 1 Study of High-Specific-Activity I–131 MIBG for Metastatic and/or Recurrent Pheochromocytoma or Paraganglioma (IB12 Phase 1 Study),'' *J Clin Endocrinol Metab,* vol. 103(1), pp. 213–220.

agree with the study's conductor [21] that the size of the study is a limitation, and with a younger, predominately white, male patient population, generalization of study results to a more diverse population may be difficult. The applicant reported that one other aspect of the patient population indicated that all 21 patients received prior anti-cancer therapy for treatment of malignant pheochromocytoma and paraganglioma tumors, which included the following: 57.1 percent (n=12) received radiation therapy including external beam radiation and conventional MIBG; 28.6 percent (n=6) received cytotoxic chemotherapy (for example, CVD and other chemotherapeutic agents); and 14.3 percent (n=3) received Octreotide.[22] Although this study's patient population illustrates a population that has failed some of the currently available therapy options, which may potentially support a finding of substantial clinical improvement for those with no other treatment options, we are unclear which patients benefited from treatment involving AZEDRA®, especially in view of the finding of a Fitzgerald, et al. study cited earlier [23] that concluded tissues previously irradiated by EBRT were found to be unresponsive to subsequent treatment with ^{131}I–MIBG radionuclide. It was not clear in the application how previously EBRT-treated patients who failed EBRT fared with the Response Evaluation Criteria in Solid Tumors (RECIST) scores, biotumor marker results, and reduction in antihypertensive medications. We also lacked information to draw the same correlation between previously CVD-treated patients and their RECIST scores, biotumor marker results, and reduction in antihypertensive medications.

The applicant asserted that the use of AZEDRA® reduces tumor size and reduces the secretion of tumor biomarkers, thereby providing important clinical benefits to patients. The IB12 study assessed the overall best tumor response based on RECIST.[24] Tumor biomarker response was assessed as complete or partial response for serum chromogranin A and total metanephrines in 80 percent and 64 percent of patients, respectively. The applicant noted that both the overall best tumor response based on RECIST and tumor biomarker response favorable results are at doses higher than 500 mCi. We noticed that tumor burden improvement, as measured by RECIST criteria, showed that none of the 21 patients achieved a complete response. In addition, although 4 patients showed partial response, these 4 patients also experienced dose-limiting toxicity with hematological events, and all 4 patients received administered doses greater than 18.5 GBq (500 mCi). We also note that, regardless of total administered activity (for example, greater than or less than 18.5 GBq (500 mCi)), 61.9 percent (n=13) of the 21 patients enrolled in the study had stable disease and 14.3 percent (n=2) of the 14 patients who received greater than administered doses of 18.5 GBq (500 mCi) had progressive disease. Finally, we also noticed that, for most tumor biomarkers, there were no dose relationship trends. While we appreciate the applicant's contention that there is no other FDA-approved drug therapy for patients who have been diagnosed with ^{131}I–MIBG avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma tumors, we have questions as to whether the overall tumor best response and overall best tumor biomarker data results from the IB12 study support a finding that the use of the AZEDRA® technology represents a substantial clinical improvement.

Finally, regarding the applicant's assertion that, based on the IB12 study data, AZEDRA® provides a safe alternative therapy for those patients who have failed other currently available treatment therapies, we note that none of the patients experienced hypertensive crisis, and that 76 percent (n=16) of the 21 patients enrolled in the study experienced Grade III or IV adverse events. Although the applicant indicated the adverse events were related to the study drug, the applicant also noted that there was no statistically significant difference between the greater than or less than 18.5 GBq administered doses; both groups had adverse events rates greater than 75 percent. Specifically, 5 of 7 patients (76 percent) who received less than or equal to 18.5 GBq administered doses, and 11 of 14 patients (79 percent) who received greater than 18.5 GBq administered doses experienced Grade III or IV adverse advents. The most common (greater than or equal to 10 percent) Grade III and IV adverse events were neutropenia, leukopenia, thrombocytopenia, nausea, and vomiting. We also note that: (1) There were 5 deaths during the study that occurred from approximately 2.5 months up to 22 months after treatment and there was no detailed data regarding the 5 deaths, especially related to the total activity received during the study; (2) there was no information about which patients received prior radiation therapy with EBRT and/or conventional MIBG relative to those who experienced Grade III or IV adverse events; and (3) the total lifetime radiation dose was not provided by the applicant. We are inviting public comments on whether the safety data profile from the IB12 study supports a finding that the use of AZEDRA® represents a substantial clinical improvement for patients who received treatment with ^{131}I–MIBG for a diagnosis of avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma tumors, given the risks for Grade III or IV adverse events.

The applicant provided study data results from the IB12B study (MIP–IB12B), an open-label, prospective 5-year follow-up, single-arm, multi-center, Phase II pivotal study to evaluate the safety and efficacy of the use of AZEDRA® for the treatment of patients who have been diagnosed with malignant and/or recurrent pheochromocytoma and paraganglioma tumors to support the assertion of substantial clinical improvement. The applicant reported that the IB12B's primary endpoint is the proportion of patients with a reduction (including discontinuation) of all anti-hypertensive medication by at least 50 percent for at least 6 months. Seventy-four patients who received at least 1 dosimetric dose of AZEDRA® were evaluated for safety and 68 patients who received at least 1 therapeutic dose of AZEDRA®, each at 500 mCi (or 8 mCi/kg for patients weighing less than or equal to 62.5 kg), were assessed for specific clinical outcomes. The applicant asserted that results from this prospective study met the primary endpoint (reduction or discontinuation of anti-hypertensive medications), as well as demonstrated strong supportive evidence from key secondary endpoints (overall tumor response, tumor biomarker response, and overall survival rates) that confers important clinical relevance to patients

[21] Noto, Richard B., et al., ''Phase 1 Study of High-Specific-Activity I–131 MIBG for Metastatic and/or Recurrent Pheochromocytoma or Paraganglioma (IB12 Phase 1 Study),'' *J Clin Endocrinol Metab,* vol. 103(1), pp. 213–220.

[22] Ibid.

[23] Fitzgerald, P.A., Goldsby, R.E., Huberty, J.P., et al., ''Malignant pheochromocytomas and paragangliomas: a phase II study of therapy with high-dose 131I-metaiodobenzylguanidine (131I–MIBG).'' *Ann N Y Acad Sci,* 2006, vol. 1073, pp. 465.

[24] Therasse, P., Arbuck, S.G., Eisenhauer, J.W., Kaplan, R.S., Rubinsten, L., Verweij, J., Van Blabbeke, M., Van Oosterom, A.T., Christian, M.D., and Gwyther, S.G., ''New guidelines to evaluate the response to treatment in solid tumors,'' *J Natl Cancer Inst,* 2000, vol. 92(3), pp. 205–16. Available at: *http://www.eortc.be/Services/Doc/RECIST.pdf.*

who have been diagnosed with malignant pheochromocytoma and paraganglioma tumors. The applicant also indicated that the use of AZEDRA® was shown to be generally well tolerated at doses administered at 8 mCi/kg. We note that the data results from the IB12B study did not have a comparator arm, making it difficult to interpret the clinical outcome data relative to other currently available therapies.

As discussed for the IB12 study, the applicant reported that antihypertension treatment was a proxy for effectiveness of the use of AZEDRA® on norepinephrine induced hypertension producing tumors. In the IB12B study, 25 percent (17/68) of patients met the primary endpoint of having a greater than 50 percent reduction in anti-hypertensive agents for at least 6 months. The applicant further indicated that an additional 16 patients showed a greater than 50 percent reduction in anti-hypertensive agents for less than 6 months, and by pooling data results from these 33 patients the applicant concluded that 49 percent (33/68) of patients achieved a greater than 50 percent reduction at any time during the study's 12-month follow-up period. The study's primary endpoint data also revealed that 11 percent of the 88 patients who received a therapeutic dose of AZEDRA® experienced a worsening of preexisting hypertension defined as an increase in systolic blood pressure to ≥160 mmHg with an increase of 20 mmHg or an increase in diastolic blood pressure ≥ 00 mmHg with an increase of 10 mmHg. All changes in blood pressure occurred within the first 24 hours post infusion. The applicant further compared its data results from the IB12B study regarding antihypertension medication and the frequency of post-infusion hypertension with published studies on MIBG and CVD therapy. The applicant noted a retrospective analysis of CVD therapy of 52 patients who had been diagnosed with metastatic pheochromocytoma and paraganglioma tumors that found only 15 percent of CVD-treated patients achieved a 50-percent reduction in anti-hypertensive agents. The applicant also compared its data results for post-infusion hypertension with literature reporting on MIBG and found 14 and 19 percent (depending on the study) of patients receiving MIBG experience hypertension within 24 hours of infusion. Comparatively, the applicant stated that the use of AZEDRA® had no acute events of hypertension following infusion. We are inviting public comments on whether these data results regarding hypertension support a finding that the use of the AZEDRA® technology represents a substantial clinical improvement, and if anti-hypertensive medication reduction is an adequate proxy for improvement in renal, cerebral, and myocardial end organ damage.

Regarding reduction in tumor burden (as defined by RECIST scores), the applicant indicated that at the conclusion of the IB12B study's 12-month follow-up period, 23.4 percent (n=15) of the 68 patients showed a partial response, 68.8 percent (n=44) of the 68 patients achieved stable disease, and 4.7 percent (n=3) of the 68 patients showed progressive disease. None of the patients showed completed response. The applicant maintained that achieving stable disease is important for patients who have been treated for malignant pheochromocytoma and paraganglioma tumors because this is a progressive disease without a cure at this time. The applicant also indicated that literature shows that stable disease is maintained in approximately 47 percent of treatment naïve patients who have been diagnosed with metastatic pheochromocytoma and paraganglioma tumors at 1 year due to the indolent nature of the disease.[25] In the IB12B study, the data results equated to 23 percent of patients achieving partial response and 69 percent of patients achieving stable disease. According to the applicant, this compares favorably to treatment with both conventional radiolabeled MIBG and CVD chemotherapy.

The applicant stated that the data results demonstrated effective tumor response rates. The applicant reported that the IB12 and IB12B study data showed overall tumor response rates of 80 percent and 92 percent, respectively. In addition, the applicant contended that the study data across both trials show that patients demonstrated improved blood pressure control, reductions in tumor biomarker secretion, and strong evidence in overall survival rates. The overall median time to death from the first dose was 36.7 months in all treated patients. Patients who received 2 therapeutic doses had an overall median survival rate of 48.7 months, compared to 17.5 months for patients who only received a single dose. We note that the IB12B study reported 12-month Kaplan-Meier estimate of survival of 91 percent, while the drug dosing study IB12 reported overall subject survival of 86 percent at 12 months, 62 percent at 24 months, 38 percent at 36 months, and 4.8 percent at 48 months. We also note that only 45 of 68 patients who received at least 1 therapeutic dose completed the 12-month efficacy phase.

The applicant indicated that comparison of the IB12B study data regarding overall survival rate with historical data is difficult due to the differences in the retrospective nature of the published clinical studies and heterogeneous patient characteristics, especially when overall survival is calculated from the time of initial diagnosis. We agree with the applicant regarding the difficulties in comparing the results of the published clinical studies, and also believe that the differences in these studies may make it more difficult to evaluate whether the use of the AZEDRA® technology improves overall survival rates relative to other therapies.

We acknowledge the challenges with constructing robust clinical studies due to the extremely rare occurrence of patients who have been diagnosed with pheochromocytoma and paraganglioma tumors. However, we are concerned that because the data for both of these studies is mainly based upon retrospective studies and small, heterogeneous patient cohorts, it is difficult to draw precise conclusions regarding efficacy. Only very limited nonpublished data from two, single-arm, noncomparative studies are available to evaluate the safety and effectiveness of AZEDRA®, leading to a comparison of outcomes with historical controls.

We are inviting public comments on whether the use of the AZEDRA® technology meets the substantial clinical improvement criterion, including with respect to the specific concerns we have raised. We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for AZEDRA® or at the New Technology Town Hall meeting.

b. CABLIVI® (caplacizumab-yhdp)

The Sanofi Company submitted an application for new technology add-on payments for CABLIVI® (caplacizumab-yhdp) for FY 2020. The applicant described CABLIVI® as a humanized bivalent nanobody consisting of two identical building blocks joined by a tri alanine linker, which is administered through intravenous and subcutaneous

[25] Hescot, S., Leboulleux, S., Amar, L., Vezzosi, D., Borget, I., Bournaud-Salinas, C., de la Fouchardiere, C., Libé, R., Do Cao, C., Niccoli, P., Tabarin, A., ''One-year progression-free survival of therapy-naive patients with malignant pheochromocytoma and paraganglioma,'' *The J Clin Endocrinol Metab,* 2013, vol. 98(10), pp. 4006–4012.

injection to inhibit microclot formation in adult patients who have been diagnosed with acquired thrombotic thrombocytopenic purpura (aTTP). The applicant stated that aTTP is a life-threatening, immune-mediated thrombotic microangiopathy characterized by severe thrombocytopenia, hemolytic anemia, and organ ischemia with an estimated 3 to 11 cases per million per year in the U.K. and U.S.[26] [27] [28] Further, the applicant stated that aTTP is an ultra-orphan disease caused by inhibitory autoantibodies to von Willebrand Factor-cleaving protease (vWFCP) also known as ''a disintegrin and metalloprotease with thrombospondin type 1 motif, member 13 (ADAMTS13),'' resulting in a severe deficiency in WFCP. The applicant further explained that von Willebrand Factor (vWF) is a key protein in hemostasis and is an adhesive, multimeric plasma glycoprotein with a pivotal role in the recruitment of platelets to sites of vascular injury. According to the applicant, more than 90 percent of circulating vWF is expressed by endothelial cells and secreted into the systemic circulation as ultra-large von Willebrand Factor (ULvWF) multimers. The applicant stated that decreased ADAMTS13 activity leads to an accumulation of ULvWF multimers, which bind to platelets and induce platelet aggregation. According to the applicant, the consumption of platelets in these microthrombi causes severe thrombocytopenia, tissue ischemia and organ dysfunction (commonly involving the brain, heart, and kidneys) and may result in acute thromboembolic events such as stroke, myocardial infarction, venous thrombosis, and early death. The applicant indicated that the aforementioned tissue and organ damage resulting from the ischemia leads to increased levels of lactate dehydrogenase (LDH), troponins, and creatinine (organ damage markers) and that faster normalization of these organ damage markers and platelet counts is believed to be linked with faster resolution of the ongoing microthrombotic process and the associated tissue ischemia. According to the applicant, in diagnoses of aTTP there is no consensual, validated surrogate marker that defines the subpopulation at greatest risk of death or significant morbidity. Therefore, the applicant stated that all patients who have been diagnosed with aTTP should be considered severe cases and treated in order to prevent death and significant morbidity.

The applicant explained that the two standard-of-care (SOC) treatment options for a diagnosis of aTTP are plasma exchange (PE), in which a patient's blood plasma is removed through apheresis and is replaced with donor plasma, and immunosuppression (for example, corticosteroids and increasingly also rituximab), which is often administered as adjunct to plasma exchange in the treatment for a diagnosis of aTTP.[29] [30] According to the applicant, despite the current SOC treatment options, acute aTTP episodes are still associated with a mortality rate of up to 20 percent, which generally occurs within the first weeks of diagnosis. The applicant asserted that, although the 20-percent mortality rate reflects substantial improvement because of PE treatment, in spite of greater understanding of disease pathogenesis and the use of newer immunosuppressants, the mortality rate has not been further improved.[31] [32] [33] [34] [35] [36] The applicant also noted that another important limitation of the currently available therapies (PE and immunosuppression) is the delayed onset of effect of days to weeks of these therapies because such therapies do not directly address the pathophysiological platelet aggregation that leads to the formation of microthrombi, which is ultimately associated with death or with the severe outcomes reported with diagnoses of aTTP. The applicant explained that despite current treatment, exacerbation and relapse occur and frequently lead to hospitalization and the need to restart daily PE treatment and optimize immunosuppression. In addition, the applicant noted that patients may experience exacerbations after discontinuing plasma exchange treatment due to continuing formation of microthrombi as a result of unresolved underlying autoimmune disease, and patients remain at risk of thrombotic complications or early death until the episode is completely resolved.[37]

According to the information provided by the applicant, CABLIVI® is administered as an adjunct to PE treatment and immunosuppressive therapy immediately upon diagnosis of aTTP through a bolus intraveneous injection for the first dose and subcutaneous injection for all subsequent doses. The recommended treatment regimen and dosage of CABLIVI® consists of administering 10 mg on the first day of treatment via intravenous injection prior to the standard plasma exchange treatment. After completion of PE treatment on the first day, a 10 mg subcutaneous injection is administered. After the first day, and for the rest of the plasma exchange treatment period, a daily 10 mg subcutaneous injection is administered following each day's PE treatment. After the PE treatment period is completed, a daily 10 mg subcutaneous injection is administered for 30 days. If the underlying immunological disease (aTTP) is not resolved, the treatment period should be extended beyond 30 days and be accompanied by optimization of immunosuppression (another SOC treatment option, in addition to PE treatment). According to the applicant and as discussed later, the use of CABLIVI® produces faster normalization of platelet count response compared to that of SOC treatment options alone. The applicant indicated that this contributes to a decrease in the

[26] Scully, M., et al., ''Regional UK TTP registry: correlation with laboratory ADAMTS 13 analysis and clinical Features,'' *Br. J. Haematol.,* 2008, vol. 142(5), pp. 819–26.

[27] Reese, J.A., et al., ''Children and adults with thrombotic thrombocytopenic purpura associated with severe, acquired Adamts13 deficiency: comparison of incidence, demographic and clinical features,'' *Pediatr. Blood Cancer,* 2013, vol. 60(10), pp. 1676–82.

[28] Terrell, D.R., et al., ''The incidence of thrombotic thrombocytopenic purpura-hemolytic uremic syndrome: all patients, idiopathic patients, and patients with severe ADAMTS–13 deficiency,'' *J. Thromb. Haemost.,* 2005, vol. 3(7), pp. 1432–6.

[29] Scully, M., et al., ''Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies,'' *Br. J. Haematol.,* 2012, vol. 158(3), pp. 323–35.

[30] George, J.N., ''Corticosteroids and rituximab as adjunctive treatments for thrombotic thrombocytopenic Purpura,'' *Am. J. Hematol.,* 2012, vol. 87 Suppl 1, pp. S88–91.

[31] *Form for Notification of a Compassionate Use Programme to the Paul-Ehrlich-Institut.*

[32] Benhamou, Y., et al., ''Cardiac troponin-I on diagnosis predicts early death and refractoriness in acquired thrombotic thrombocytopenic purpura. Experience of the French Thrombotic Microangiopathies Reference Center,'' *J. Thromb. Haemost.,* 2015, vol. 13(2), pp. 293–302.

[33] Han, B., et al., ''Depression and cognitive impairment following recovery from thrombotic thrombocytopenic purpura,'' *Am. J. of Hematol.,* 2015, vol. 90(8), pp. 709–14.

[34] Rajan, S.K., ''BMJ Best Practice; Thrombotic thrombocyopenic purpura,'' May 27, 2016.

[35] Goel, R., et al., ''Prognostic risk-stratified score for predicting mortality in hospitalized patients with thrombotic thrombocytopenic purpura: nationally representative data from 2007 to 2012,'' Transfusion, 2016, vol. 56(6), pp. 1451–8.

[36] Rock, G.A., Shumak, K.H., Buskard, N.A., et al., ''Comparison of plasma exchange with plasma infusion in the treatment of thrombotic thrombocytopenic purpura. Canadian Apheresis Study Group,'' *N Engl J Med,* 1991, vol. 325, pp. 393–397.

[37] Goel, R., et al., ''Prognostic risk-stratified score for predicting mortality in hospitalized patients with thrombotic thrombocytopenic purpura: nationally representative data from 2007 to 2012,'' Transfusion, 2016, vol. 56(6), pp. 1451–8.

length of the SOC treatment period with respect to the number of days of PE treatment, the mean length of intensive care unit stays, and the mean length of hospitalizations.

With respect to the newness criterion, CABLIVI® received FDA approval on February 6, 2019, for the treatment of adult patients who have been diagnosed with aTTP, in combination with plasma exchange and immunosuppressive therapy. According to information provided by the applicant, CABLIVI® was previously granted Fast Track and Orphan Drug designations in the United States for the treatment of aTTP by the FDA and Orphan Drug designation in Europe for the treatment of aTTP. Currently, there are no ICD–10–PCS procedure codes to uniquely identify procedures involving CABLIVI®. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the administration of CABLIVI® beginning in FY 2020.

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, according to the applicant, CABLIVI® is a first-in-class therapy with an innovative mechanism of action. The applicant explained that CABLIVI® binds to the A1 domain of vWF and specifically inhibits the interaction between vWF and platelets. Furthermore, the applicant indicated that in patients who have been diagnosed with aTTP, proteolysis of ULvWF multimers by ADAMTS13 is impaired due to the presence of inhibiting or clearing anti-ADAMTS13 auto-antibodies, resulting in the persistence of the constitutively active A1 domain and, as a consequence, platelets spontaneously bind to ULvWF and generate microvascular blood clots in high shear blood vessels. The applicant noted that CABLIVI® is able to interact with vWF in both its active (that is, ULvWF multimers or normal multimers activated through immobilization or shear stress) and inactive forms (that is, multimers prior to conformational change of the A1 domain), thereby immediately blocking the interaction of vWF with the platelet receptor (GPIb-IX–V) and further preventing spontaneous interaction of ULvWF with platelets that would lead to platelet microthrombi formation in the microvasculature, local schemia and platelet consumption. The applicant highlighted that this immediate platelet-protective effect differentiates CABLIVI® from slower-acting therapies, such as PE and immunosuppressants, which need days to exert their effect. The applicant explained that PE acts by removing ULvWF and the circulating auto-antibodies against ADAMTS13, thereby replenishing blood levels of ADAMTS13, while immunosuppressants aim to stop or reduce the formation of auto-antibodies against ADAMTS13.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant believed that potential cases representing patients who may be eligible for treatment involving CABLIVI® would be assigned to the same MS– DRGs as cases representing patients who receive SOC treatment for a diagnosis of aTTP. As explained below in the discussion of the cost criterion, the applicant believed that potential cases representing patients who may be eligible for treatment involving CABLIVI® would be assigned to MS–DRGs that contain cases representing patients who were diagnosed with aTTP and received therapeutic PE procedures during hospitalization.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, there are no other specific therapies approved for the treatment of patients diagnosed with aTTP. As stated earlier, according to the applicant, patients who have been diagnosed with aTTP have two currently available SOC treatment options: PE, in which a patient's blood plasma is removed through apheresis and is replaced with donor plasma, and immunosuppression (for example, corticosteroids and increasingly rituximab), which is administered as an adjunct to PE in the treatment of aTTP. The applicant further explained that immunosuppression consisting of glucocorticoids is often administered as adjunct to PE in the initial treatment of a diagnosis of aTTP,[38] [39] but their use is based on historical evidence that some patients with limited symptoms might respond to corticosteroids alone.[40] [41] The applicant noted that there have been no studies specifically comparing treatment involving the combination of PE with corticosteroids, versus PE alone; that they are not specifically approved for the treatment of a diagnosis of aTTP, and that other immunosuppressive agents used to treat a diagnosis of aTTP, such as rituximab, have not been studied in properly controlled, double-blind studies. The applicant also noted that rituximab, aside from not being licensed for the treatment of a diagnosis of aTTP, is not fully effective during the first 2 weeks of treatment, with a reported delay of onset of its effect that may extend up to 27 days, with at least 3 to 7 days needed to achieve adequate B-cell depletion (given the B-cells may also contain ADAMTS13 antibodies), and even longer to restore ADAMTS13 activity levels.[42] [43]

Based on the applicant's statements as summarized above, the applicant believes that CABLIVI® provides a new treatment option for patients who have been diagnosed with aTTP. However, it is not clear that CABLIVI® would involve the treatment of a different type of disease or a different patient population. As stated earlier, according to the applicant, patients who have been diagnosed with aTTP have two SOC treatment options for a diagnosis of aTTP: PE, in which a patient's blood plasma is removed through apheresis and is replaced with donor plasma, and immunosuppression (for example, corticosteroids and increasingly also rituximab), which is administered as an adjunct to PE in the initial treatment for a diagnosis of aTTP. Therefore, it appears that CABLIVI® is used to treat the same or similar type of disease (a diagnosis of aTTP) and a similar patient population as currently available treatment options.

We are inviting public comments on whether CABLIVI® is substantially similar to other technologies and whether CABLIVI® meets the newness criterion.

[38] Scully, M., et al., ''Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies,'' *Br. J. Haematol.,* 2012, vol. 158(3), pp. 323–35.

[39] George, J.N., ''Corticosteroids and rituximab as adjunctive treatments for thrombotic thrombocytopenic Purpura,'' *Am. J. Hematol.,* 2012, vol. 87 Suppl 1, pp. S88–91.

[40] Bell, W.R., et al., ''Improved survival in thrombotic thrombocytopenic purpura-hemolytic uremic Syndrome. Clinical experience in 108 patients,'' *N. Engl. J. Med.,* 1991, vol. 325(6), pp. 398–403.

[41] Phillips, E.H., et al., ''The role of ADAMTS–13 activity and complement mutational analysis in differentiating acute thrombotic microangiopathies,'' *J. Thromb. Haemost.,* 2016, vol. 14(1), pp. 175–85.

[42] Coppo, P., ''Management of thrombotic thrombocytopenic purpura,'' *Transfus Clin Biol.,* Sep 2017, vol. 24(3), pp. 148–153.

[43] Froissart, A., et al., ''Rituximab in autoimmune thrombotic thrombocytopenic purpura: A success story,'' *Eur. J. Intern. Med.,* 2015, vol. 26(9), pp. 659–65.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. In order to identify the range of MS–DRGs that cases representing potential patients who may be eligible for treatment using CABLIVI® may map to, the applicant identified all MS–DRGs for patients who had been hospitalized for a diagnosis of aTTP. Specifically, the applicant searched the FY 2017 MedPAR file for Medicare fee-for-service inpatient hospital claims submitted between October 1, 2016 and September 30, 2017, and identified potential cases by ICD–10–CM diagnosis code M31.1 (Thrombotic microangiopathy) and ICD–10–PCS procedure codes 6A550Z3 (Pheresis of plasma, single) and 6A551Z3 (Pheresis of plasma, multiple). The applicant noted that it excluded cases with an ICD–10–CM diagnosis code of D59.3 (Hemolytic-uremic syndrome).

This resulted in 360 cases spanning 61 MS–DRGs, with approximately 67.2 percent of all potential cases mapping to the following 5 MS–DRGs:

MS–DRG	MS–DRG title
MS–DRG 545	Connective Tissue Disorders with MCC.
MS–DRG 546	Connective Tissue Disorders without CC.
MS–DRG 547	Connective Tissue Disorders without CC/MCC.
MS–DRG 682	Renal Failure with MCC.
MS–DRG 698	Other Kidney and Urinary Tract Diagnoses with MCC.

Using the 242 identified cases that mapped to the top 5 MS–DRGs above, the average case-weighted unstandardized charge per case was $188,765. The applicant then standardized the charges and then removed historic charges for items that are expected to be avoided for patients who receive treatment involving CABLIVI®. The applicant determined that 31 percent of historical routine bed charges, 65 percent of historical ICU charges, and 38 percent of historical blood administration charges (which includes charges for therapeutic PE) would be reduced because of the use of CABLIVI®, based on the findings from the Phase III clinical study HERCULES. The applicant indicated it used the FY 2017 MedPAR file to determine the appropriate amount of charges to remove. The applicant then inflated the adjusted standardized charges by 8.864 percent utilizing the 2-year inflation factor published by CMS in the FY 2019 IPPS/LTCH PPS final rule to adjust the outlier threshold (83 FR 41722). (We note that this figure was revised in the FY 2019 IPPS/LTCH PPS final rule correction notice. The corrected final 2-year inflation factor is 1.08986 (83 FR 49844). We further note that even when using the corrected final rule values to inflate the charges, the average case-weighted standardized charge per case exceeded the average case-weighted threshold amount.) The applicant explained that the anticipated price for CABLIVI®'s indication for the treatment of patients who have been diagnosed with aTTP, in combination with plasma exchange and immunosuppressive therapy, has yet to be determined and, therefore, no charges for CABLIVI® were added in the analysis. Based on the FY 2019 IPPS/LTCH PPS final rule correction notice data file thresholds for FY 2020, the applicant determined the average case-weighted threshold amount was $49,904. The final inflated average case-weighted standardized charge per case was $145,543. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion. We are inviting public comments on whether CABLIVI® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that it believes that CABLIVI® represents a substantial clinical improvement compared to the use of currently available treatments (PE and immunosuppressants) because it: (1) Significantly reduces time to platelet count response, which is consistent with the halting of platelet consumption in microthrombi; (2) significantly reduces the number of patients with aTTP-related death, recurrence of aTTP-related episodes, or a major thromboembolic event; (3) reduces mortality; (4) reduces the proportion of patients with recurrence of aTTP diagnoses; (5) reduces the proportion of patients who develop refractory disease; (6) reduces the number of days of PE; (7) reduces the mean length of intensive care unit stay and the mean length of hospitalization; and (8) shows a trend of more rapid normalization of organ damage markers. The applicant provided further detail regarding these assertions, referencing the results of Phase II and Phase III studies and an integrated efficacy analysis of both studies.

The applicant reported that the Phase II study was a randomized, single-blind, placebo controlled study entitled ALX–0681–2.1/10 (TITAN) that examined the efficacy and safety of the use of CABLIVI® compared to a placebo, with the primary endpoint being achievement of a statistically significant reduction in time to platelet count response. Seventy-five patients, 66 of which were white, (19 to 72 years old, with a mean of 41.6 years old; 44 women and 31 men) with an episode of aTTP were randomized 1:1 to receive either CABLIVI® (n=36) or placebo (n=39), in addition to daily PE.[44] Patients received their first dose of CABLIVI® administered through intravenous injection prior to the first PE, followed by daily doses administered subcutaneously after each PE. After discontinuing PE, daily doses of CABLIVI® administered through subcutaneous injection were continued for 30 days. The median treatment duration with CABLIVI® was 36 days.

According to the applicant, significantly more patients in the treatment arm met the primary endpoint [95 percent Confidence Interval (CI) (3.78, 1.28)]. The applicant indicated that the time to platelet count response improvement constitutes a significant substantial clinical improvement because it demonstrated that patients treated with CABLIVI® were 2.2 times more likely to achieve an acceptable time to platelet count response than patients receiving treatment with the placebo. Additionally, the applicant noted that exacerbation of aTTP occurred in fewer patients who were treated with CABLIVI® (8.3 percent) than placebo (28.2 percent). During the 1-month follow-up period, 8 relapses (defined as a recurrence more than 30 days after discontinuing PE) occurred in the CABLIVI® group with 7 of the relapses occurring within 10 days of

[44] Peyvandi, F., Scully, M., Kremer Hovinga, J.A., Cataland, S., Knöbl, P., Wu, H., Artoni, A., Westwood, J.P., Mansouri Taleghani, M., Jilma, B., Callewaert, F., Ulrichts, H., Duby, C., Tersago, D., TITAN Investigators, ''Caplacizumab for Acquired Thrombotic Thrombocytopenic Purpura,'' *N Engl J Med.,* February 11, 2016, vol. 374(6), pp. 511–22. PMID: 26863353.

discontinuing the study drug. In all seven of the relapses, ADAMTS13 activity was still severely suppressed at the end of the treatment period, evidence of ongoing underlying immunological disease and indicating an imminent risk of another relapse. The applicant explained that according to post-hoc analyses, the group of patients who were treated with CABLIVI® compared to placebo showed a decrease in the percentage of patients with refractory disease (0 percent versus 10.8 percent), a reduction in the number of days of PE (7.7 days versus 11.7 days) and a trend to more rapid normalization of organ damage markers (lactate dehydrogenase, cardiac troponin I and serum creatinine). Finally, the applicant noted that there were no deaths in the group of patients who were treated with CABLIVI®. However, 2 of the 39 placebo-treated patients (5.1 percent) died.

The applicant explained that the Phase III study was a randomized, double-blind, placebo controlled study entitled ALX0681–C301 (HERCULES) that examined the efficacy and safety of the use of CABLIVI® compared to a placebo, with the primary endpoint being achievement of a statistically significant reduction in time to platelet count response. One hundred forty-five patients (18 to 79 years old, with a mean of 46 years old, 100 women and 45 men), with an episode of aTTP were randomized 1:1 to receive either CABLIVI® (n=72) or placebo (n=73) in addition to daily PE and immunosuppression.[45] The applicant explained that patients received a single 10 mg CABLIVI® intravenous injection or placebo prior to the first PE, followed by a daily CABLIVI® 10 mg subcutaneous injection or placebo after completion of PE, for the duration of the daily PE treatment period and for 30 days thereafter. According to the applicant, if at the end of this treatment period (daily PE treatment period and 30 days after) there was evidence of persistent underlying immunological disease activity (indicative of an imminent risk for recurrence), treatment could be extended weekly for a maximum of 4 weeks, together with optimization of immunosuppression. The applicant indicated that patients who experienced a recurrence while undergoing study drug treatment were switched to open-label CABLIVI® and they were again treated for the duration of daily PE treatment and for 30 days thereafter. If at the end of this treatment period (daily PE treatment period and 30 days after) there was evidence of ongoing underlying immunological disease, open-label treatment with CABLIVI® could be extended weekly for a maximum of 4 weeks, together with optimization of immunosuppression. Patients were followed for 28 days after discontinuation of treatment. Upon recurrence during the follow-up period (that is, after all study drug treatment had been discontinued), there was no re-initiation of the study drug because recurrence at this point was treated according to the SOC. The median treatment duration with CABLIVI® in the double-blind period was 35 days.

According to the applicant, patients in the treatment arm were more likely to achieve platelet count response at any given time point, compared to the placebo [95 percent CI (1.1, 2.2)]. The applicant believed that this constitutes a significant substantial clinical improvement because patients who were treated with CABLIVI® were 1.55 times more likely to achieve platelet count response at any given time point, compared to placebo. The applicant also indicated that, compared to placebo, treatment with CABLIVI® resulted in a 74 percent reduction in the number of patients with aTTP-related death, recurrence of aTTP diagnosis, or a major thromboembolic event, during the study drug treatment period ($p<0.0001$).

The applicant noted that the proportion of patients with a recurrence of an aTTP diagnosis in the Phase III study period (that is, the drug treatment period plus the 28-day follow-up after discontinuation of the drug treatment) was 67 percent lower in the CABLIVI® group (12.7 percent) compared to the placebo group (38.4 percent) ($p<0.001$). The applicant also indicated that in all 6 patients in the CABLIVI® group who experienced a recurrence of an aTTP diagnosis during the follow-up period (that is, a relapse), ADAMTS13 activity levels were less than 10 percent at the end of the study drug treatment, indicating that the underlying immunological disease was still active at the time CABLIVI® was discontinued. Furthermore, the applicant stated that there were no patients who were treated with CABLIVI® that had refractory disease (defined as absence of platelet count doubling after 4 days of standard treatment and elevated LDH), compared to 3 patients (4.2 percent) who had refractory disease that were treated with placebo. The applicant also explained that a trend to faster normalization of the organ damage markers lactate dehydrogenase, cardiac troponin I and serum creatinine was observed in patients who were treated with CABLIVI®. The applicant noted that during the study drug treatment, there were no deaths in patients who were treated with CABLIVI®, while 3 of the 73 placebo-treated patients (4.1 percent) died. Finally, the applicant stated that during the Phase III study drug treatment period, treatment with CABLIVI® resulted in a 38 percent reduction in the mean number of PE treatment days versus placebo (reduction of 3.6 days) and a 41 percent reduction in the mean volume of PE (reduction of 14.6L). Furthermore, treatment with CABLIVI® resulted in a 65 percent reduction in the mean length of ICU stay (reduction of 6.3 days) and a 31 percent reduction in the mean length of hospitalization (reduction of 4.5 days) during the Phase III study drug treatment period.

The applicant submitted integrated data from the blinded periods of the Phase II and Phase III studies that show a statistically significant difference in favor of CABLIVI® (n=108) in time to platelet count response compared to placebo (n=112). The applicant indicated that patients who were treated with CABLIVI® were 1.65 times more likely to achieve platelet count response at any given time point during the blinded period than patients who were treated with placebo (95 percent CI: 1.23, 2.20; $p<0.001$). Additionally, according to the applicant, integrated data from the blinded periods of the Phase II and Phase III studies showed that compared to placebo, treatment with CABLIVI® resulted in a 72.6 percent reduction in the percentage of patients with aTTP-related death, a recurrence of a aTTP diagnosis, or at least one treatment-emergent major thromboembolic event during the blinded treatment period ($p<0.0001$). More specifically, the applicant indicated that during the blinded treatment period no aTTP-related deaths occurred in the CABLIVI® group compared to 4 aTTP-related deaths in the placebo group ($p<0.05$), treatment with CABLIVI® resulted in an 84.0 percent reduction in the proportion of patients with a recurrence of a aTTP diagnosis (exacerbation, relapse) during the blinded treatment period ($p<0.0001$), and treatment with CABLIVI® resulted in a reduction of 40.8 percent in the proportion of patients with at least one treatment-emergent major thromboembolic event during the blinded treatment period.

According to the applicant, pooled data from the two studies showed that none of the patients who were treated with CABLIVI® developed refractory disease (that is, absence of platelet count doubling after 4 days of standard

[45] Scully, M., et al., ''Treatment of Acquired Thrombotic Thrombocytopenic Purpura with Caplacizumab,'' *N. Engl. J. Med.,* (In Press).

treatment and elevated LDH) compared to 7 patients (6.3 percent; 7/112) who were treated with placebo during the blinded period ($p<0.01$). Finally, the applicant noted that across both studies, treatment with CABLIVI® resulted in a 37.5 percent reduction in the mean number of days of PE treatment (reduction of 3.9 days).

Although the applicant asserts that CABLIVI® represents a substantial clinical improvement compared to the use of currently available treatments (PE and immunosuppressants), we are concerned that the Phase II TITAN and Phase III HERCULES studies may not provide enough evidence to support that the use of CABLIVI® represents a substantial clinical improvement.

Regarding the Phase II TITAN study, we are concerned that because 66 of the 75 patients in the study population were white, the results of the study may not be generalizable to a more diverse population that may be at risk for diagnosis of aTTP. Additionally, we note that CABLIVI® was associated with fewer aTTP exacerbations during therapy, but was associated with more aTTP exacerbations after therapy was discontinued, suggesting a lack of effect on long-term anti-ADAMTS13 antibody levels. Although this is consistent with CABLIVI®'s mechanism of action, we are concerned that without long-term data to determine the impact of adjunct use of CABLIVI® on exacerbations and relapse it may be difficult to determine if the use of CABLIVI® represents a substantial clinical improvement over existing therapy.

Based on data from the Oklahoma TTP–HUS Registry, the incidence of aTTP is approximately three cases per 1 million adults per year.[46] Additionally, the median age for a diagnosis of aTTP is 41, with a wide range between 9 years old and 78 years old. We acknowledge the challenges with constructing robust clinical studies due to the extremely rare occurrence of patients who have been diagnosed with aTTP. However, regarding the Phase III HERCULES study, we are nonetheless concerned that the study population was small, 145 people. Additionally, it is unclear if the response rate may differ in those who have a *de novo* diagnosis versus those with recurrent disease. We note that PE treatment alone has been attributed to an 80 percent survival rate,[47] and because CABLIVI® is given in combination with or after SOC therapies, we are concerned that we may not have sufficient information to determine the extent to which the study results are attributable to the use of CABLIVI®. Furthermore, with the follow-up period for the Phase III HERCULES study being only 28 days, we are concerned that there is a lack of long-term data. In the absence of long-term data, we are concerned about the impact of the use of CABLIVI® on the relapse rate beyond the overall study period, including the 28-day follow-up period.

Finally, although both the Phase II and III studies consisted of key secondary endpoints such as death or major thromboembolic events, we are concerned that these endpoints were not clearly defined. We also are concerned that the studies did not appear to account for other clearly defined endpoints such as heart attack, stroke, a bleeding episode, and power calculations for the expected differences in such endpoints that would be biologically important.

We are inviting public comments on whether CABLIVI® meets the substantial clinical improvement criterion.

Below we summarize and respond to a written comment we received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for CABLIVI®.

Comment: The applicant stated that during the New Technology Town Hall meeting questions were asked regarding the design of the Phase III HERCULES study, specifically regarding treatments that were administered during the different arms of the study. To address those questions, the applicant summarized the methodology of the Phase III HERCULES study by indicating that 145 patients with an acute episode of aTTP who had received one PE treatment were randomized 1:1 to placebo (73 patients), or 10 mg of CABLIVI® (72 patients), in addition to receiving daily PE treatment and corticosteroids. The applicant explained that a single intravenous dose of 10 mg of the study drug was given before the first PE performed during the study and a single 10 mg subcutaneous dose was given the same day following completion of that day's PE treatment. The applicant further stated that a subcutaneous dose was given daily during the PE treatment period and 30 days thereafter. The applicant noted that, if at the end of this period there was evidence of ongoing disease, such as suppressed ADAMTS13 activity, investigators were encouraged to extend the blinded treatment for a maximum of 4 weeks in combination with optimization of immunosuppression. In addition, the applicant indicated that all patients entered a 28-day treatment-free follow-up period after the last dose of the study drug. The applicant explained that the primary endpoint was time to platelet count response, defined as platelet count greater than or equal to $150 \times 10/L$ with discontinuation of daily PE treatment within 5 days. Further, the applicant stated that there were four key secondary endpoints, hierarchically ranked: (1) The proportion of patients with aTTP-related death, aTTP recurrence, or at least one major thromboembolic event during the study drug treatment period (a blinded, independent committee adjudicated aTTP-related deaths and major thromboembolic events); (2) the proportion of patients with a recurrence during the entire study period, including the follow-up period; (3) the proportion of patients with refractoriness to therapy, defined as absence of platelet count doubling after 4 days of treatment and LDH still above normal; and (4) the time to normalization of 3 organ damage markers: LDH, cardiac troponin I and serum creatinine.

Response: We appreciate the information provided by the applicant. We will take this information into consideration when deciding whether to approve new technology add-on payments for CABLIVI® for FY 2020.

c. CivaSheet®

CivaTech Oncology, Inc. submitted an application for new technology add-on payments for CivaSheet® for FY 2020. CivaSheet® received FDA clearance of a 510(k) premarket notification on August 29, 2014. CivaSheet® was approved as a ''sealed source'' by the Nuclear Regulatory Commission (NRC) and added to the Registry of Radioactive Sealed Source and Devices on October 24, 2014. On May 9, 2018, CivaSheet® was registered by the American Association of Physicists in Medicine (AAPM) on the ''Joint AAPM/IROC Houston Registry of Brachytherapy Sources Complying with AAPM Dosimetric Prerequisites.'' According to the applicant, inclusion on this AAPM registry is a long-standing requirement imposed on brachytherapy sources used

[46] Reese, J.A., Muthurajah, D.S., Kremer-Hovinga, J.A., Vesely, S.K., Terrell, D.R., George, J.N., ''Children and adults with thrombotic thrombocytopenic purpura associated with severe, acquired Adamts13 deficiency: comparison of incidence, demographic and clinical features,'' *Pediatr Blood Cancer,* October 2013, vol. 60(10), pp. 1676–82, Epub June 1, 2013.

[47] Rock, G.A., Shumak, K.H., Buskard, N.A., et al., ''Comparison of plasma exchange with plasma infusion in the treatment of thrombotic thrombocytopenic purpura. Canadian Apheresis Study Group,'' *N Engl J Med,* 1991, vol. 325, pp. 393–397.

in all National Cancer Institute clinical trials and that all other available brachytherapy sources are included on this registry. According to the applicant, CivaSheet® was not commercially distributed among IPPS hospitals until May 2018, after meeting the requirements for inclusion in the AAPM registry. Therefore, according to the applicant the ''newness'' period for the CivaSheet®, if approved for FY 2020 new technology add-on payments, should commence on May 9, 2018. Based on this information, we believe the newness period for CivaSheet® would begin on May 9, 2018. However, we are seeking public comments on whether inclusion on the AAPM registry is an appropriate indicator of the first availability of the CivaSheet® brachytherapy sources on the U.S. market and whether the date of inclusion on the AAPM registry is appropriate to consider as the beginning of the newness period for CivaSheet®.

CivaSheet® is intended for medical purposes to be placed into a body cavity or tissue as a source for the delivery of radiation therapy. CivaSheet® is indicated for use as a brachytherapy source for the treatment of selected localized tumors. The device may be used either for primary treatment or for the treatment of residual disease after excision of the primary tumor. CivaSheet® may be used concurrently, or sequentially, with other treatment modalities, such as external beam radiation therapy or chemotherapy. We note that the applicant has submitted a request for approval for a unique ICD–10–PCS procedure code to describe procedures involving the use the CivaSheet® device, beginning in FY 2020.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, according to the applicant, CivaSheet® does not have a similar mechanism of action in comparison to existing brachytherapy technologies. The applicant asserted that the unique construction and configuration of the CivaSheet® device permits delivery of radiation intra-operatively in a highly targeted fashion. The applicant explained that the CivaSheet® is cut to size in the operation room (OR) and conformed to the patient's anatomy and surgical site, which allows radiation to be delivered to the resected tumor bed margins at the time of the original surgery. The applicant further explained that, it is generally believed that ''hot'' spots should be avoided in the delivery of radiotherapy because they lead to complications, citing the finding that ''[i]n brachytherapy, dose homogeneity is difficult to achieve, but efforts to minimize ''hot'' spots have been regarded as virtuous and implant-planning guidelines were developed to assist in this regard.'' [48] The applicant stated that implants are rarely geometrically perfect and, to avoid under-dosing some parts of the target volume, it may be necessary to create ''hot spots'' in other parts of the anatomy. However, as a result, a ''hotter'' dose compared to that achievable with external beam technologies can be delivered to the intended area. In contrast, the applicant indicated that CivaSheet®'s unidirectional configuration substantially reduces the dose delivered to neighboring radiosensitive structures. The applicant further stated that other forms of radiation delivery do not have these capabilities, and no other shielded low-dose radiation (LDR) sources are currently available on the market. According to the applicant, external beam radiation generally cannot be delivered intra-operatively, partly because dosage requirements make this impractical and potentially risky and because appropriate aiming cannot be computed in the timeframe of a performed surgery.

The applicant believed that, in the absence of the use of the CivaSheet® device, a patient requiring radiation therapy to accompany surgery would most likely receive radiation therapy as an outpatient service following the inpatient hospitalization after surgery. Moreover, the applicant stated that not only does this typically require multiple, fractionated treatments, in some cases, outpatient external beam radiation may not be possible due to excessive toxicity to normal surrounding tissues. According to the applicant, radiation therapy can be delivered intra-operatively directly to surgical margins through use of a linear accelerator. However, the applicant stated that these technologies deliver radiation in a single ''flash,'' whereas the CivaSheet® device enables the delivery of radiation over time, increasing the efficacy of the radiation therapy.

Further, the applicant stated that external beam radiation devices have a fixed ball or cone-shaped applicator, which does not necessarily conform well to the irregular shapes of surgical cavities or permit effective screening of adjacent tissues. Additionally, the applicant stated that this form of radiation therapy requires a specialized linear accelerator and a specially shielded operating room, which the applicant believes restricts its use to IPPS-exempt cancer centers.

The applicant further stated that, in the past, cylindrical brachytherapy seeds have been used with various mesh products as a form of intra-operative radiation therapy (IORT). However, according to the applicant, the use of cylindrical brachytherapy seeds used with various mesh products has not developed as part of standard clinical practice. According to the applicant, patients treated with previous cylindrical brachytherapy seeds faced considerable challenges with toxicity from the unfocused, unshielded seed sources when placed in proximity of sensitive organs.[49] Additionally the surgical meshes previously used were not designed to maximize source orientation and spacing, and also ran the risk of source dispersion as the mesh degraded.[50]

The applicant maintains that the CivaSheet® is the first low-dose radiation (LDR) brachytherapy device designed specifically for the delivery of IORT. CivaSheet®'s individual brachytherapy sources are flat with a gold shielding on one side of the seed, a design that focuses radiation in one direction, in contrast to the cylindrical shape of LDR brachytherapy seeds, which emit radiation in all directions. According to the applicant, properties of the flat, gold-shielded sources and the bioabsorbable polymer encapsulation make the CivaSheet® uniquely suited for intra-operative delivery. As such, the applicant asserted that the CivaSheet® does not have a similar mechanism of action when compared to existing LDR brachytherapies.

With regard to the second criterion, whether a product is assigned to the same or similar MS–DRG, the applicant

[48] Bhadrasain, M.D., Vikram, Shivaji, Ph.D., Deore, Beitler, M.D., Jonathan J., Sood, M.D., Brij, Mullokandov, Ph.D., Eduard, Kapulsky, Ph.D., Alexander, Fontenla, Ph,d, Doracy P, ''The relationship between dose heterogeneity (''hot'' spots) and complications following high-dose rate brachytherapy,'' *Int. J. Radiation Oncology Biol. Phys.,* 1999, vol. 43, no. 5, pp. 983–987.

[49] Rivard, Mark J., ''Low energy brachytherapy sources for pelvic sidewall treatment,'' abstract presented at the ABS 2016 Annual Meeting.

[50] Seneviratne, Danushka, et al., ''The CivaSheet: The new frontier of intraoperative radiation therapy or a pricer alternative to LDR brachytherapy,'' Advances in Radiation Oncology, 2018, vol. 3, pp. 87–91.

asserted that patients who may be eligible for treatment using the CivaSheet® include hospitalized patients having tumors removed from the pancreas, colon and anus, pelvic area, head and neck, soft tissue sarcomas, non-small-cell lung cancer, ocular melanoma, atypical meningioma and retroperitoneum and that cases involving the use of the CivaSheet® would map primarily into the following MS–DRGs:

MS–DRG	MS–DRG title
11	Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy with MCC.
12	Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy with CC.
13	Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy without CC/MCC.
129	Major Head and Neck Procedures with CC/MCC or Major Device.
130	Major Head and Neck Procedures without CC/MCC.
133	Other Ear, Nose, Mouth and Throat O.R. Procedures with CC/MCC.
134	Other Ear, Nose, Mouth and Throat O.R. Procedures without CC/MCC.
326	Stomach, Esophageal and Duodenal Procedures with MCC.
327	Stomach, Esophageal and Duodenal Procedures with CC.
328	Stomach, Esophageal and Duodenal Procedures without CC/MCC.
329	Major Small and Large Bowel Procedures with MCC.
330	Major Small and Large Bowel Procedures with CC.
331	Major Small and Large Bowel Procedures without CC/MCC.
332	Rectal Resection with MCC.
334	Rectal Resection without CC/MCC.
405	Pancreas, Liver and Shunt Procedures with MCC.
406	Pancreas, Liver and Shunt Procedures with CC.
407	Pancreas, Liver and Shunt Procedures without CC/MCC.
576	Skin Graft Except for Skin Ulcer or Cellulitis with MCC.
577	Skin Graft Except for Skin Ulcer or Cellulitis with CC.
578	Skin Graft Except for Skin Ulcer or Cellulitis without CC/MCC.
653	Major Bladder Procedures with MCC.
654	Major Bladder Procedures with CC.
734	Pelvic Evisceration, Radical Hysterectomy and Radical Vulvectomy with CC/MCC.
735	Pelvic Evisceration, Radical Hysterectomy and Radical Vulvectomy without CC/MCC.
736	Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC.
739	Uterine, Adnexa Procedures for Non-Ovarian/Adnexal Malignancy with MCC.
740	Uterine, Adnexa Procedures for Non-Ovarian/Adnexal Malignancy with CC.
741	Uterine, Adnexa Procedures for Non-Ovarian/Adnexal Malignancy without CC/MCC.
826	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with MCC.
827	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with CC.
828	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure without CC/MCC.

We believe that cases involving the use of existing technologies would be assigned to these same MS–DRGs listed above.

With regard to the third criterion, whether the use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, clinical conditions that may require use of the CivaSheet® include treatment of the same patient population as those who have been diagnosed with a variety of types of cancer, including pancreatic cancer, colorectal cancer, anal cancer, pelvic area/gynecological cancer, retroperitoneal sarcoma and head and neck cancers.

The applicant asserted that the CivaSheet® device is not substantially similar to any existing technology because it uses a unique mechanism of action, when compared to existing LDR brachytherapy technologies, to achieve a therapeutic outcome and, therefore, meets the newness criterion.

We are inviting public comments on whether the CivaSheet® device meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. To determine the MS–DRGs that potential cases representing patients who may be eligible for treatment involving CivaSheet® would map to, the applicant identified all MS–DRGs for cases that included ICD–10–CM diagnosis codes for either pancreatic cancer, colorectal cancer, anal cancer, pelvic area/gynecological cancer, retroperitoneal sarcoma and head and neck cancers as a primary or secondary diagnosis. Based on the FY 2017 MedPAR Hospital Limited Data Set (LDS), the applicant identified a total of 22,835 potential cases. The applicant limited its analyses to the most relevant 32 MS–DRGs, which represented 80 percent of all the cases. The applicant excluded the following cases: Statistical outliers which the applicant defined as 3 standard deviations from the geometric mean, HMO cases and claims submitted only for graduate medical education payments and cases at hospitals that were not included in the FY 2019 IPPS/LTCH PPS final rule impact file (the applicant noted that these are predominately cancer hospitals not subject to the IPPS). After applying the trims above, the applicant identified 17,173 remaining cases.

Using the 17,173 cases, the applicant determined an average case-weighted unstandardized charge per case of $122,565. The applicant standardized the charges for each case and inflated each case's charges from FY 2017 to FY 2019 by applying the outlier charge inflation factor of 1.085868 from the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20581). The applicant indicated that the current average cost of the CivaSheet® device is $24,132.86. The applicant then added charges for CivaSheet® by taking the cost of the device and converting it to a charge by dividing the costs by the national average CCR of 0.309 for implants from the FY 2019 IPPS/LTCH PPS final rule (83 FR 41273). The applicant calculated an average case-weighted standardized charge per case of $188,897 using the percent distribution of MS–DRGs as case weights. Based on this analysis, the applicant determined that the final inflated average case-weighted

standardized charge per case for CivaSheet® exceeded the average case-weighted threshold amount of $87,446 by $101,451.

We note that the inflation factor used by the applicant was the proposed 2-year inflation factor, which was discussed in the FY 2019 IPPS/LTCH PPS final rule summation of the calculation of the FY 2019 IPPS outlier charge inflation factor for the proposed rule (83 FR 41718 through 41722). The final 2-year inflation factor published in the FY 2019 IPPS/LTCH PPS final rule was 1.08864 (83 FR 41722), which was revised in the FY 2019 IPPS/LTCH PPS final rule correction notice to 1.08986 (83 FR 49844). However, we note that even when using either the final rule values or the corrected final rule values published in the correction notice to inflate the charges, the final inflated average case-weighted standardized charge per case for CivaSheet® would exceed the average case-weighted threshold amount. We are inviting public comments on whether the CivaSheet® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that CivaSheet® represents a substantial clinical improvement over existing technologies because it provides the following: (1) Improved local control of different cancers; [51] (2) reduced rate of device-related complications; [52] (3) reduced rate of radiation toxicity; [53] (4) decreased future hospitalizations; [54] (5) decreased rate of subsequent therapeutic interventions; [55] (6) improvement in back pain and appetite in pancreatic cancer patients [56] and (7) improved local control for pancreatic cancer patients.[57]

With regard to improved local control of different cancers, the applicant provided the clinical outcomes results of a 20-month report of a patient who had been diagnosed with leiomyosarcoma of the pelvic sidewall.[58] According to the report, the purpose of the report was to document the experience of using the CivaSheet® implant as adjuvant intraoperative treatment in a patient who had been diagnosed with locally advanced leiomyosarcoma of the lateral pelvic sidewall. The patient analyzed in this report is a 62-year-old African American male who was found to have a mass incidentally in the left pelvic sidewall. The patient presented with lower abdominal pain, hematuria, and lower left flank pain radiating to the left groin. A CT scan revealed a mass in the left pelvic sidewall that measured 8.1 x 6.4 x 3.7 cm, with encasement of the left common iliac vein and no distant metastasis. A biopsy revealed a high-grade leiomyosarcoma. Given his advanced clinical stage and iliac vein encasement, neoadjuvant pelvic radiotherapy with IMRT, surgical resection with reconstruction, and a boost with intraoperative LDR brachytherapy were performed. The patient was treated with pelvic IMRT (50.4 Gy/28 fractions). The patient then underwent gross total resection and the CivaSheet® was implanted intraoperatively. The patient recovered well from the interventions, according to the report. At 20 months after implantation of the LDR brachytherapy device, clinical evaluations and CT imaging surveillance demonstrated no evidence of residual disease, according to the report.

With regard to reducing the rate of device-related complications, the applicant summarized four case series. In the four case series, the CivaSheet® device was used to treat: (1) Axillary squamous cell carcinoma; [59] (2) retroperitoneal sarcoma; [60] [61] [62] (3) gastric signet ring adenocarcinoma; (4) pancreatic cancer; and (5) other abdominal malignancies. There were 13 patients associated with these 4 case series.

Seneviratne, et al.'s case series report documented experience with the use of the CivaSheet® device in a 78 year old male patient who had been diagnosed with axillary squamous cell carcinoma. According to the case series report, prior to surgery a dose of 58 Gy, prescribed to the 95 percent isodose line (±5 percent), was delivered in 2 Gy fractions with 3-dimensional conformal EBRT with concurrent weekly administration of cisplatin 40 mg/m2 at an outside facility. Magnetic resonance imaging scans obtained 3 months post-treatment revealed that the mass had decreased in size to 3.8 cm x 2.5 cm x 3.9 cm, but maintained encasement of the axillary artery, axillary vein, and several inferior branches of the brachial plexus. Concerns with regard to increased toxicity to the axillary structures discouraged further EBRT, and the CivaSheet® device was implanted immediately post tumor resection. Given that microscopic disease within formerly irradiated tissue was being treated, a prescription dose of 20 Gy at 5 mm from the surface of the mesh was considered adequate because of its delivery of a biologically effective dose (BED)-10 of 39.8 Gy and equivalent dose (EQD)-2 of 33.2 Gy to the tumor bed, while limiting the D2cc for the brachial plexus to a BED3 of 27.9 Gy and EQD2 of 16.7 Gy, based on post implant analysis. According to the Seneviratne, et al. analysis, this approach allowed for a significantly limited dose to be delivered to the brachial plexus. A composite dose constraint of D2cc of 75 Gy was selected on the basis of recent data showing elevated clinical brachial plexopathy rates beyond this threshold. This constraint was met with an estimated composite EQD2 of 74.7 Gy, which, according to the applicant, would not have been obtainable with EBRT to a tumor bed EQD2 of greater than or equal to 30 Gy. The patient was discharged on the same day with instructions on wound care and radiation safety. According to the applicant, the incision healed well, with no signs of infection, seroma, or lymphadenopathy during monthly follow-up visits. At the 8-month follow-up visit, the patient was documented to only have minor shoulder pain. Seneviratne, et al., also discussed their views on the advantages of the use of

[51] Castaneda SA, Emrich J, Bowne WB, Kemmerer EJ, Sangani R, Khalili M, Rivard MJ, Poli J. ''Clinical outcomes using a novel directional Pd-103 brachytherapy device: 20-month report of a patient with leiomyosarcoma of the pelvic sidewall.'' ACRO 2018 Annual Meeting.

[52] Seneviratne, D., McLaughlin, C., Todor, D., Kaplan, B., Fields, E., ''The CivaSheet: The new frontier of intraoperative radiation therapy or a pricier alternative to LDR brachytherapy?,'' Advances in Radiation Oncology, 2018, vol. 3, pp. 87–91.

[53] Howell, K.J., Meyer, J.E., Rivard, M.J., et al., ''Initial Clinical Experience with Directional LDR Brachytherapy for Retroperitoneal Sarcoma,'' submitted *Int J of Rad Onc Biol Phys,* 2018.

[54] Cavanaugh, S.X., Rothley, D.J., Richman, C., ''Directional LDR Intraoperative Brachytherapy for Head and Neck Cancer,'' Presented at ABS 2017 Annual Meeting.

[55] On file at CivaTech.

[56] Ibid.

[57] Yoo, S.S., Todor, D.A., Myers, J.M., Kaplan, B.J., Fields, E.C., ''Widening the therapeutic window using an implantable, uni-directional LDR brachytherapy sheet as a boost in pancreatic cancer,'' ASTRO 2018 Annual Meeting San Antonio, TX.

[58] Castaneda, S.A., Emrich, J., Bowne, W.B., Kemmerer, E.J., Sangani, R., Khalili, M., Rivard, M.J., Poli, J., ''Clinical outcomes using a novel directional Pd-103 brachytherapy device: 20-month report of a patient with leiomyosarcoma of the pelvic sidewall,'' ACRO 2018 Annual Meeting.

[59] Seneviratne, D., McLaughlin, C., Todor, D., Kaplan, B., Fields, E., ''The CivaSheet: The new frontier of intraoperative radiation therapy or a pricier alternative to LDR brachytherapy?,'' Advances in Radiation Oncology, 2018, vol. 3, pp. 87–91.

[60] Zhen, H., Turian, J.V., Sen, N., et al.,''Initial clinical experience using a novel Pd-103 surface applicator for the treatment of retroperitoneal and abdominal wall malignancies,'' Advances in Radiation Oncology, 2018, vol. 3, pp. 216–220.

[61] Howell, K.J., Meyer, J.E., Rivard, M.J., et al., ''Initial Clinical Experience with Directional LDR Brachytherapy for Retroperitoneal Sarcoma,'' submitted Int J of Rad Onc Biol Phys, 2018.

[62] Turian, J.V., ''Emerging Technologies for IORT: Unidirectional Planar Brachytherapy Sources,'' Presented at AAPM 2017 Annual Meeting.

the CivaSheet® device, which include its bio-absorbability, ease of visualization with imaging, potential for intra-operative customization, ability to complement various treatment approaches including EBRT and surgical resection, and ease of implantation with minimal training.

To further substantiate its assertions of a reduced rate of device-related complications regarding the CivaSheet® device, the applicant stated that its malleability is likely to be particularly useful in treating irregularly shaped surgical cavities, such as those created after breast lumpectomies or pelvic side wall resections. According to the applicant, the CivaSheet® device also overcomes several shortcomings observed even among those LDR mesh devices that use the same isotope. According to the applicant, as the vicryl sutures of traditional LDR mesh devices bend and curve around irregular surfaces during placement, the spacing and orientation of the radioactive seeds may be altered, leading to unpredictable variations in isodose geometry. The applicant stated that, in contrast, the polymer encapsulation of the Pd-103 Civa seeds before embedding within the membrane allows the sources to maintain their orientation in space and deliver radiation in accordance with the predetermined geometry. According to the applicant, additionally, unlike older LDR mesh devices that run the risk of source dispersion after mesh degradation, the polymer encapsulation allows the seeds to maintain their placement even as the membrane is absorbed over time. In this same case study, Seneviratne, et al., stated that a 3-month post implantation imaging of the CivaSheet® device demonstrated that the radioactive source geometry had remained stable since the initial implantation.

The applicant also provided Howell, et al.'s case series results of six patients diagnosed with recurrent retroperitoneal sarcoma who had been treated with the use of the CivaSheet® device to support its claims of reduced rate of toxicity and improved local control. Similar to the Seneviratne, et al. case series report, Howell, et al.'s case series' report also noted concerns regarding prior EBRT, costs associated with intra-operative radiation therapy both for the patient and the hospital, and concerns of at-risk surrounding anatomic structures. Given these concerns, Howell, et al.'s case series report also investigated LDR brachytherapy using CivaSheet®. Amongst the six patients observed, five patients had diagnoses of recurrent disease in the retroperitoneum or pelvic side wall; one patient had a diagnosis of locally-advanced leiomyosarcoma with no previous treatment. Regarding prior treatment, two patients had prior EBRT at first diagnosis. Four patients received neoadjuvant EBRT prior to surgery in addition to treatment involving CivaSheet® brachytherapy. The LDR brachytherapy dose was determined using radiobiological calculations of biological effective dose (BED) based on the linear-quadratic model and EQD2 values. An LDR brachytherapy dose of 20 to 60 Gy (36 Gy mean) was administered, corresponding to BED values of 15 to 53 Gy (29 Gy mean) and EQD2 values of 12 to 43 Gy (23 Gy mean). Because the goal was to provide a conformal radiation boost for an additional 15 to 20 Gy EQD2, the prescribed absorbed doses were considered appropriate. All patients were followed by CT scan to assess implant migration, observed radiation-related toxicities, and evidence for local recurrence between 2.5 weeks and 3 months. No evidence of implant migration or radiation-related toxicities was found. Based on these results, the study concluded that LDR directional brachytherapy delivered a targeted dose distribution that was successfully used to treat retroperitoneal sarcoma, and that the utilized device is an important option for the treatment of patients who have been diagnosed with retroperitoneal sarcoma having close/positive surgical margins and/or in combination with EBRT to optimize local control.

Two other case series, by Zhen, H. et al.,[63] and Turian, et al.,[64] were submitted by the applicant to support the assertion of reduced rate of device-related complications. Both case series assessed the use of LDR brachytherapy using the CivaSheet® device in the tumor bed given the same clinical challenges outlined in case series observed and investigated in the Seneviratne, et al., and Howell, et al. analyses in patients previously treated with chemoradiation protocols and in patients who had been diagnosed with recurrent tumors close to important functional tissues. Both case series assessed LDR brachytherapy using the CivaSheet® device in the treatment of different cancers like retroperitoneal sarcomas, pancreatic cancers, and gastric singnet ring adenocarcinoma or other abdominal carcinomas. Both case series followed the patients with CT imaging sometime between 2.5 weeks and 86 weeks. Both case series' study concluded that LDR brachytherapy with the use of the CivaSheet® device was a feasible alternative treatment modality for the cancers treated in each case series. According to Zhen, et al., an advantage of using the CivaSheet® device is that the CivaDot sheets can be easily cut to any size and shape at the time of implant. The author further stated that the CivaDot sheet is malleable and can conform to curved surfaces. This device characteristic, according to the author, gives the physician more flexibility to treat tumor beds with irregular shapes and surface curvatures compared with electron beam cylindrical applicators, thereby reducing the rate of device-related complications. However, the analysis by Zhen, et al. also indicated that a limitation in dosimetric evaluation using CT imaging is related to the inability to identify the orientation of the individual CivaDot mainly because of limited resolution and metal artifact caused by the gold plating. CivaDot orientation is inferred from the fact that all dots are embedded in a membrane that is sutured to the tumor bed and because the post-implant CT scan shows the shape of the CivaSheet® seeds being maintained. Also, Zhen, et al. noted that surgical clips could be mistakenly identified as CivaDots. The analysis by Zhen, et al. recommended that the use of surgical clips should be minimized.

With regard to the reduced rate of toxicity, the applicant provided a clinical case series by Howell, et al.[65] to show that shielding healthy tissues while irradiating the tumor bed after surgical resection was achieved by providing a conformal radiotherapy, a novel Pd-103 low-dose rate (LDR) brachytherapy device. Methods and materials of the case include the following: The LDR brachytherapy device was considered for patients who had been diagnosed with recurrent retroperitoneal sarcoma, had received prior radiotherapy to the area, and/or had anatomy concerning for high-risk margins predicted for recurrence after resection. The case series included the clinical conclusions for five patients who had been diagnosed with recurrent disease in the retroperitoneum or pelvic side wall, one patient who had been diagnosed with locally-advanced leiomyosarcoma with no previous treatment, two patients who had prior

[63] Zhen, H., Turian, J.V., Sen, N., et al.,''Initial clinical experience using a novel Pd-103 surface applicator for the treatment of retroperitoneal and abdominal wall malignancies'', Advances in Radiation Oncology, 2018, vol. 3, pp. 216–220.

[64] Turian, J.V., ''Emerging Technologies for IORT: Unidirectional Planar Brachytherapy Sources,'' Presented at AAPM 2017 Annual Meeting.

[65] Howell, K.J., Meyer, J.E.,Rivard, M.J. et al., ''Initial Clinical Experiences with Directional LDR Brachytherapy for Retroperitoneal Sarcomo, submitted to *Int J of Rad Onc Biol Phys,* 2018.

EBRT at first diagnosis, and four patients who received neoadjuvant EBRT prior to surgery in combination with brachytherapy. The LDR brachytherapy dose was determined using radiobiological calculations of biological effective dose (BED) based on the linear-quadratic model and EQD2 values. An LDR brachytherapy dose of 20 to 60 Gy (36 Gy mean) was administered, corresponding to BED values of 15 to 53 Gy (29 Gy mean) and EQD2 values of 12 to 43 Gy (23 Gy mean). Because the goal was to provide a conformal radiation boost for an additional 15 to 20 Gy EQD2, the prescribed absorbed doses were considered appropriate. According to the applicant, results showed that radiation was delivered to the at-risk tissues with minimal irradiation of adjacent healthy structures or structures occupying the surgical cavity after tumor resection. According to the applicant, clinical outcomes indicated feasibility for surgical implantation and promising results in comparison to current standards-of-care. The device did not migrate over the course of follow-up and there were no observed radiation-related toxicities.

The Howell, et al. clinical case series concluded that LDR directional brachytherapy delivered a targeted dose distribution that was successfully used to treat retroperitoneal sarcoma and that the utilized device is an important option for the treatment of patients who have been diagnosed with retroperitoneal sarcoma having close/positive surgical margins and/or in combination with EBRT to optimize local control.

The applicant also cited three additional case series to support their assertions of reduced rate of device-related complications and reduced rate of radiation toxicity. The first is on file at CivaTech in which they indicated that more than 60 patients, since 2015, had CivaSheet® implanted with no reported device-related toxicity in patients previously treated with maximal EBRT. No other details were provided by the applicant. The second case series by Taunk, et al.[66] assessed the use of CivaSheet® in three patients who had been diagnosed with colorectal adenocarcinoma who had undergone prior induction chemotherapy and neoadjuvant chemoradiation. CivaSheet® was placed in the tumor bed and patients were followed with CT imaging to assess implant migration, 30- and 90-day radiation toxicity and local recurrence. One patient was deemed not a feasible candidate because the CivaSheet® could not be uniformly opposed to the sacrum due to the degree of concavity. The other two patients underwent successful CivaSheet® implantation, and at 30 days showed stability of the device and no apparent toxicity. In the final additional case series from Rivard, et al.,[67] a single patient who had been diagnosed with pelvic side wall cancer (type not indicated) was implanted with CivaSheet® and the CivaSheet® dose distributions were compared to those of conventional low-dose rate, low-energy photon-emitting brachytherapy seeds (that is, palladium 103, Iodine-125, and Cesium-131). According to the applicant, results suggest gold-shielding CivaDots attenuate radiation for directional brachytherapy and CivaSheet® provides a therapeutic target dose, while substantially minimizing critical structure doses. In this specific case study, the applicant stated that the use of CivaSheet® showed decreased radiation to adjacent organs, such as the bowel and the bladder.

With regard to decreasing the number of future hospital visits, the applicant provided a poster presentation presented at the American Brachytherapy Society 2017 Annual Meeting. The purpose of this study was to investigate the feasibility of using intra-operative directional brachytherapy for the treatment of squamous cell carcinoma of the oropharynx. The study included a single patient who had received a prior course of external beam radiation therapy of 70 Gy in 2015. Due to positive margins near the carotid after the resection, and the increased risk of additional external radiation, brachytherapy was considered as a treatment option. CivaSheet® was used for the implant. The Pd-103 sources were spaced 8 mm apart on a rectangular grid. Unidirectional dose was achieved by a 0.05 mm thick gold disk-shaped foil on the reverse side of each source. A dose of 120 Gy at 5 mm depth was prescribed. After the resection, the entire polymer sheet was placed on the treatment area to determine the needed dimensions. The CivaSheet® device was then removed and cut to size with scissors leaving 26 Pd-103 sources remaining. The surgeon used 3.0 vicryl sutures for attachment in a concave shape over the carotid artery, where there was a positive margin. The gold foil was positioned to protect the neck flap and closure. The surgical team completed the procedure and the patient recovered without any complications.

Results of the study showed that the sources remained in position in a concave array pattern. Due to the dose fall-off of Pd-103, the calculated dose to critical structures was minimized. Because the surgical implant of the CivaDot sheet proceeded as expected with no complications and the post-implant plan indicated that the CivaSheet® remained in position with the radioactive side contacting the treatment area, the applicant asserts that future hospital visits will be decreased because the patient will not return for EBRT.

With regard to decreases in the rate of subsequent therapeutic interventions, the applicant stated that the standard-of-care for most patients undergoing surgery is typically preceded or followed by a form of external beam radiation therapy. A typical course of intensity modulated radiation therapy (IMRT) is 25 to 30 fractions (separate treatments) delivered over the course of 3 to 6 weeks. The applicant stated that, for some patients, CivaSheet® will be the only form of radiation therapy they will receive. CivaSheet® is implanted in one procedure and radiation is locally delivered over the course of several weeks, while the sources provide a continuous dose and later decay. The device is not removed and no additional follow-up visits are required for the patient to receive therapeutic intervention. According to the applicant, use of CivaSheet® can avoid the time and expense of dozens of radiation therapy visits over the course of several weeks as compared to EBRT. The applicant further stated that the published clinical data provided with its application[68] shows that the use of CivaSheet® is an effective and safe combinational treatment to external beam radiation therapy. According to the applicant, radiation oncologists can use CivaSheet® to increase the dose of radiation that can be delivered to a tumor margin, without increasing toxicity and that this may reduce the odds that a patient experiences cancer recurrence.[69] [70] [71] The applicant also

[66] Taunk, N.K., Cohen, G., Taggar, A.S., et al., ''Preliminary Clinical Experience from a Phase I Feasibility Study of a Novel Permanent Unidirectional Intraoperative Brachytherapy Device,'' ABS 2017 Annual Meeting.

[67] Rivard, M.J., ''Low-energy brachytherapy sources for pelvic sidewall treatment,'' Presented at ABS 2016 Annual Meeting.

[68] Taunk, N.K., Cohen, G., Taggar, A.S., et al., ''Preliminary Clinical Experience from a Phase I Feasibility Study of a Novel Permanent Unidirectional Intraoperative Brachytherapy Device,'' ABS 2017 Annual Meeting.

[69] Rivard, Mark J., ''Low energy brachytherapy sources for pelvic sidewall treatment,'' abstract presented at the ABS 2016 Annual Meeting.

[70] Yoo, S.S., Todor, D.A., Myers, J.M., Kaplan, B.J., Fields, E.C., ''Widening the therapeutic

Continued

asserted that the targeted radiation approach has demonstrated no toxic effects for patients. The applicant further stated that other forms of radiation have a known rate of complications and toxicity that result in the need for additional therapies and interventions (for example, topical creams for skin reddening, and medicine for pain). The applicant indicated that there has been no change in concomitant medications prescribed because of the use of the CivaSheet® implant either on or off trial. The applicant did not link these claims to any of the studies provided with its application. In addition, the applicant asserts that, of the case studies they provided, there have been no instances of therapeutic interventions to resolve an issue that was induced by the use of the CivaSheet® device to deliver radiation.[72] [73] [74]

With regard to improvement in back pain and appetite (compared to baseline) in pancreatic cancer patients, the applicant asserted that patients answered standardized, international questionnaire EORTC QLQ–C30 and PANC26 and that these results are on file at CivaTech. The applicant provided the baseline, 70 days post-operative and 98 days postoperative patient responses to ''Have you ever had back pain?'' Baseline response: 1.5; 70 days post-operative response: 1.0 and 98 days post-operative response: 1.0. The applicant also provided baseline, 70 days post-operative and 98 days post-operative patient responses to ''Were you restricted in the amounts of food you could eat as a result of your disease or treatment?'' Baseline response: 2.5; 70 days postoperative response: 1.0 and 98 days postoperative response: 1.0. (Response Values: 1.0 = ''Not at all''; 2.0 = ''A little''; 3.0 = ''Quite a bit''; 4.0 = ''Very much'').

With regard to improved local control for pancreatic cancer patients, the applicant provided the results of a dosimetric study entitled, ''Widening the Therapeutic Window Using an Implantable, Uni-directional LDR Brachytherapy Sheet as a Boost in Pancreatic Cancer Case Series,'' a poster presented at the ASTRO 2018 Annual Meeting. According to background information in the applicant's poster, pancreatic patients often undergo neoadjuvant chemotherapy and chemoradiation in preparation for surgical resection of the tumor. In addition, oftentimes after neoadjuvant therapy there are inflammatory changes that, unfortunately, hinder pre-operative imaging and create the potential for unreliable determination of tumor resection. Accompanying the potentially unreliable determination of tumor resectability are patient concerns when positive retroperitoneal margins have close proximity to major vasculature. The applicant noted that additional EBRT boost, initiated post operatively, is an option, but difficult given bowel constraints and the difficulty in identifying the area at highest risk. Given these constraints associated with treating pancreatic cancers, the purpose of this study was to demonstrate the ability of the LDR brachytherapy CivaSheet® device to deliver a focal high-dose boost, targeted to the area at highest risk in patients who received neoadjuvant chemoradiation. This dosimetric case series consisted of four patients who had been diagnosed with borderline resectable pancreatic cancer who received neoadjuvant FOLFIRINOX followed by gemcitabine-based chemoradiotherapy (chemoRT) to 50.4 Gy in 28 fractions with dose prescribed to the gross tumor plus a 1 cm margin. According to the poster provided by the applicant, after neoadjuvant therapy, the multidisciplinary team was concerned for close or positive margin resection. Using the CivaSheet® device, a 38 Gy EQD2 dose to 5 mm depth was implanted in these patients and a total dose of 88.4 Gy was delivered to the targeted tissue. Post-operatively, patients had a CT scan to identify the tumor bed contour, as well as the contour of surrounding at-risk organs; the small bowel (SB) was contoured as the bowel bag and included the entire peritoneal cavity. Following the CT scan, brachytherapy plans, as well as EBRT boost plans, were created for each patient. A dose-volume histogram (DVH) from initial 3D treatment plans for all patients showed the SB volume receiving 45 Gy (V45) was a median of 78.2 cc (range 61.7–107.1 ccs) and maximum bowel doses were a median of 53.2 Gy, range 53.1–53.6 Gy. According to the applicant, the V45 for SB should be less than 195 cc, with a maximum of less than or equal to 58 Gy to prevent SB obstruction, fistula and perforation. According to the applicant, with the CivaSheet® device, the boost dose was dramatically increased while SB exposure was marginal at about 1/10th of the prescription dose. For the target, the CivaSheet® delivered the prescription dose to 5 mm depth with a large inhomogeneous dose throughout the tumor bed with the minimum dose of 38 Gy. Dosimetric comparison of a CivaSheet® tumor bed boost and a Stereotactic Body Radiation Therapy (SBRT) tumor bed boost to the SB was 9.6 Gy compared to 24 Gy for external beam plan. According to the applicant, the conclusions from this case series are that applying a brachytherapy uni-directional source to the area at highest risk can serve to improve the therapeutic index by improving the local control and minimizing toxicities in pancreatic cancer patients after neoadjuvant therapy.

With regard to whether CivaSheet® represents a substantial clinical improvement relative to other brachytherapy technologies currently available, we are concerned that all of the supporting data appear to be feasibility studies substantiating the use of the CivaSheet® in different cancers and difficult anatomic locations. We also are concerned that there do not appear to be any comparisons to other current treatments, nor any long-term follow-up with comparisons to currently available therapies. We are inviting public comments on whether CivaSheet® meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the CivaSheet® or at the New Technology Town Hall meeting.

d. CONTEPO™ (Fosfomycin for Injection)

Nabriva Therapeutics U.S., Inc. submitted an application for new technology add-on payments for CONTEPO™ for FY 2020. CONTEPO™ is intended to treat complicated urinary tract infections (cUTIs) caused by multi-drug resistant (MDR) pathogens in hospitalized patients. CONTEPO™ has not yet received FDA approval. The FDA has accepted the applicant's New Drug Application (NDA) using its Priority Review expedited program.

Complicated urinary tract infections are characterized by chills, rigors, or fever (temperature of greater than or equal to 38.0 °C); elevated white blood cell count (greater than 10,000/mm^3), or

window using an implantable, uni-directional LDR brachytherapy sheet as a boost in pancreatic cancer,'' ASTRO 2018 Annual Meeting San Antonio, TX.

[71] Howell, K.J., Meyer, J.E., Rivard, M.J., et al., ''Initial Clinical Experience with Directional LDR Brachytherapy for Retroperitoneal Sarcoma,'' submitted *Int J of Rad Onc Biol* Phys, 2018.

[72] Ibid.

[73] Rivard, Mark J., ''Low energy brachytherapy sources for pelvic sidewall treatment,'' abstract presented at the ABS 2016 Annual Meeting.

[74] Yoo, S.S., Todor, D.A., Myers, J.M., Kaplan, B.J., Fields, E.C., ''Widening the therapeutic window using an implantable, uni-directional LDR brachytherapy sheet as a boost in pancreatic cancer,'' ASTRO 2018 Annual Meeting San Antonio, TX.

left shift (greater than 15 percent immature PMNs); nausea or vomiting; dysuria, increased urinary frequency, or urinary urgency; and lower abdominal pain or pelvic pain. A related condition, acute pyelonephritis (AP), is characterized by chills, rigors, or fever (temperature of greater than or equal to 38.0 °C); elevated white blood cell count (greater than 10,000/mm^3), or left shift (greater than 15 percent immature PMNs); nausea or vomiting; dysuria, increased urinary frequency, or urinary urgency; flank pain; and costo-vertebral angle tenderness on physical examination. Risk factors for infection with drug-resistant organisms do not, on their own, indicate a cUTI.[75] The applicant stated that CONTEPO™ would offer a new potential first-line treatment for patients with cUTIs suspected to be caused by MDR pathogens in the United States.

The applicant stated that CONTEPO™ is an epoxide intravenous antibiotic that eradicates bacteria by inhibiting the bacteria's ability to form cell walls, which are critical for a cell's survival and growth. The applicant asserted that CONTEPO™ offers a broad spectrum of bactericidal Gram-negative and Gram-positive activity, including activity against Extended-spectrum β-lactamase (ESBL)-producing Enterobacteriaceae, as well as other contemporary MDR organisms.

The applicant noted that there are currently no ICD–10–PCS procedure codes that could be used to uniquely identify the use of CONTEPO™. However, the applicant stated that potential cases representing patients who may be eligible to receive treatment through the administration of CONTEPO™ could be identified with ICD–10–PCS codes 3E03329 (Introduction of Other Anti-infective into Peripheral Vein, Percutaneous Approach) or 3E04329 (Introduction of Other Anti-infective into Central Vein, Percutaneous Approach). The applicant has submitted a request for approval for a new ICD–10–PCS procedure code to uniquely identify CONTEPO™ administration in FY 2020.

The applicant has recommended that CONTEPO™ be administered as follows: 6 g every 8 hours by intravenous (IV) infusion over 1 hour for up to 14 days for patients 18 years of age or older, with an estimated creatinine clearance (CrCl) greater than or equal to 50 mL/min. Dosage adjustment is required for patients whose creatinine clearance is 50 mL/min or less.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether the product uses a similar mechanism of action, the applicant stated that CONTEPO™'s mechanism of action differentiates it from other approved injectable antibiotics. The applicant reports that CONTEPO™, as an injectable epoxide and sole antibiotic class member, inhibits an early step in peptidoglycan biosynthesis by covalently binding to MurA, an enzyme that catalyzes the first committed critical step in a bacteria's ability to form a cell wall and, therefore, the cell's survival and growth. The applicant indicated that CONTEPO™'s mechanism of action is unique in comparison to all other injectable antibiotics by working at a different and earlier stage of cell wall synthesis inhibition, such that the cell wall lacks suitable integrity and the bacteria die quickly. The applicant further stated that because of this unique mechanism of action, CONTEPO™ lacks cross resistance with other existing classes of intravenous antibiotics.

With respect to the second criterion, whether the product is assigned to the same or a different MS–DRG, the applicant asserted that patients who may be eligible to receive treatment involving CONTEPO™ include hospitalized patients who have been diagnosed with a cUTI. The applicant noted that the relevant existing ICD–10–PCS procedure codes (3E3329 and 3E04329) map to many existing MS–DRGs. The applicant lists the most common of these MS–DRGs as MS–DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC); MS–DRG 690 (Kidney and Urinary Tract Infections without MCC); MS–DRG 698 (Other Kidney and Urinary Tract Diagnoses with MCC); MS–DRG 872 (Septicemia or Severe Sepsis without MV >96 hours without MCC); MS–DRG 689 (Kidney and Urinary Tract Infections with MCC); MS–DRG 699 (Other Kidney and Urinary Tract Diagnoses with CC); MS–DRG (683 Renal Failure with CC); MS–DRG 682 (Renal Failure with MCC); MS–DRG 853 (Infectious and Parasitic Diseases with O.R. Procedure with MCC); and MS–DRG 291 (Heart Failure and Shock with MCC). Cases involving the use of CONTEPO™ would likely be assigned to the same MS–DRGs to which cases involving treatment with comparator drugs are assigned.

With respect to the third criterion, whether the use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted that the use of CONTEPO™ would treat a different patient population than existing and currently available treatment options. While many drugs treat the broad population of patients who have been diagnosed with cUTIs, the applicant asserts that increasing rates of Enterobacteriaceae resistance to fluoroquinolones and ESBLs have limited both classes use as first-line therapies among inpatients with infections caused by suspected or confirmed MDR pathogens. The applicant cited a study, which estimates the prevalence of drug resistance among uropathogens isolated from hospitalized patients in the United States. According to the study, there is a more than a two-fold increase in ESBL-producing *E. coli* (from 3.3 percent to 8 percent), ESBL-producing *K. pneumoniae* (from 9.1 percent to 18.6 percent), and CRE (from 0 percent to 2.3 percent) causing UTIs in the period between 2000 and 2009.[76] The applicant further asserts that the use of CONTEPO™ will also treat a different diseased patient population than the currently available therapies. According to the applicant, CONTEPO™'s unique mechanism of action amongst injectable antibiotics and novel class allows the use of CONTEPO™ to reach different and expanded patient populations, particularly those patients who have been diagnosed with a cUTI that may have pathogens resistant or suspected resistance to ESBL and CRE, or fluoroquinolone resistance. Further, the applicant stated that CONTEPO™'s stewardship value to clinicians is as a carbapenem-sparing potential therapy that may result in real world reductions in CRE resistance, further sparing a last-line of defense for critically ill patient populations, which due to unique resistance profiles, the applicant asserts constitute a different population than is currently treated.

Based on the applicant's statements as summarized above, the applicant believes that CONTEPO™ is not substantially similar to any existing intravenous antibiotic treatment. However, we are concerned with respect to the first criterion as to whether the mechanism of action described by the

[75] Hooton, T. and Kalpana, G., 2018, ''Acute complicated urinary tract infection (including pyelonephritis) in adults,'' In A. Bloom (Ed.), UpToDate. Available at: *https://www.uptodate.com/contents/acute-complicated-urinary-tract-infectionincluding-pyelonephritis-in-adults.*

[76] Shorr, A.F., Zilberberg, M.D., Micek, S.T., Kollef, M.H., ''Prediction of Infection Due to Antibiotic-Resistant Bacteria by Select Risk Factors for Health Care-Associated Pneumonia,'' *Arch Intern Med,* 2008, vol. 168(20), pp. 2205–10.

applicant is unique to CONTEPO™ or whether it may be similar to other drugs that inhibit cell wall development, including penicillins, cephalosporins, and carbapenems. With respect to the second criterion, we believe that potential cases involving the use of CONTEPO™ would be assigned to the same MS–DRGs as cases involving comparator antibiotics. Finally, with respect to the third criterion, we are concerned whether CONTEPO™ treats a unique patient population, as the applicant asserts. While the variety of antibiotic resistance patterns certainly warrants a varied armamentarium for clinicians, there are many existing antimicrobials that are approved to generally treat cUTIs and MDR pathogens. We are concerned as to whether hospitalized patients who have been diagnosed with cUTIs, including those with MDR pathogens, would constitute a unique patient population, given that there are existing treatment options for these patients. This concern as to whether the technology may be considered to treat a new patient population seems particularly relevant for an antibiotic due to the evolving nature of global bacterial resistance patterns, and, specifically, the applicant's assertion that the use of CONTEPO™ would be a new tool in the growing battle against MDR bacteria infections. We are inviting public comments on whether CONTEPO™ is substantially similar to any existing technologies and whether it meets the newness criterion, including with respect to the concerns we have raised.

With regard to the cost criterion, the applicant used the FY 2017 MedPAR Limited Data Set (LDS) to assess the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving CONTEPO™ would most likely be mapped. According to the applicant, CONTEPO™ is anticipated to be indicated for the treatment of hospitalized patients who have been diagnosed with cUTIs. The applicant identified 199 ICD–10–CM diagnosis code combinations that identify hospitalized patients who have been diagnosed with a cUTI. Searching the FY 2017 MedPAR data file for these ICD–10–CM diagnosis codes resulted in a total of 508,821 potential cases that span 559 unique MS–DRGs, 510 of which contained more than 10 cases. The applicant excluded MS–DRGs with minimal volume (that is, 10 cases or less) from the cohort of the analysis (a total of 201 cases and 49 MS–DRGs), and this resulted in a total of 508,620 cases across 461 MS–DRGs.

Using 100 percent of the potential cases (508,620), the applicant determined an average case-weighted unstandardized charge per case of $59,009. The applicant standardized the charges for each case and inflated each case's charges by applying the FY 2019 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.08864 (83 FR 41722). (We note that the 2-year inflation factor was revised in the FY 2019 IPPS/LTCH PPS final rule correction notice to 1.08986 (83 FR 49844). However, we further note that even when using the corrected final rule values to inflate the charges, the average case-weighted standardized charge per case for each scenario exceeded the average case-weighted threshold amount.) The applicant examined associated charges per MS–DRG and removed charges for potential antibiotics that may be replaced by the use of CONTEPO™. Specifically, the applicant identified 5 antibiotics currently used for the treatment of patients who have been diagnosed with a cUTI and calculated the cost of each of these drugs for administration over a 14-day inpatient hospitalization. Because patients who have been diagnosed with a cUTI would typically only be treated with one of these antibiotics at a time, the applicant estimated an average of the 14-day cost for the 5 antibiotics. The applicant then took this cost and converted it to a charge by dividing the costs by the national average CCR of 0.191 for drugs from the FY 2019 IPPS/LTCH PPS final rule (83 FR 41273). The applicant calculated an average case-weighted standardized charge per case of $71,333 using the percent distribution of MS–DRGs as case-weights. Based on this analysis, the applicant determined that the final inflated average case-weighted standardized charge per case for CONTEPO™ exceeded the average case-weighted threshold amount of $52,203 by $19,130.

Because of the large number of cases included in this cost analysis, the applicant conducted sensitivity analyses. In these analyses, the applicant repeated the cost analysis above using only the top 75 percent of cases, the top 20 MS–DRGs, and the top 10 MS–DRGs. In these three additional sensitivity analyses, the final inflated average case-weighted standardized charge per case for CONTEPO™ exceeded the average case-weighted threshold amount by $14,949, $14,230, and $13,620, respectively. We are inviting public comments on whether CONTEPO™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the results from the CONTEPO™ clinical trial clearly establish that CONTEPO™ represents a substantial clinical improvement in the treatment of antibiotic resistant infections as compared to currently available treatments. Specifically, the applicant asserted that the use of CONTEPO™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, and the use of CONTEPO™ significantly improves clinical outcomes for this patient population compared to currently available treatments. The applicants cited the ZEUS Study, a multi-center, randomized, parallel-group, double-blind Phase II/III trial of 464 patients designed to evaluate safety, tolerability, efficacy and pharmacokinetics of the use of CONTEPO™ in the treatment of hospitalized adults who have been diagnosed with a cUTI or AP at 92 global sites in 16 countries. Hospitalized adults who have been diagnosed with suspected or microbiologically confirmed cUTI/AP were randomized 1:1 to receive treatment with either CONTEPO™ or piperacillin-tazobactam (PIP–TAZ) for a fixed 7-day course (no oral switch); patients who had been diagnosed with concomitant bacteremia could receive up to 14 days. Diagnosis was based on pyuria and cUTI or AP with at least two of the following signs and symptoms: Chills, rigors, or warmth associated with fever, nausea or vomiting, dysuria, lower abdominal pain or pelvic pain, or acute flank pain. Patients who had been diagnosed with a cUTI had at least one of the following: Use of intermittent or indwelling bladder catheterization, functional or anatomical abnormality of urogenital tract, complete or partial obstructive uropathy, azotemia or chronic urinary retention in men. Baseline urine culture specimen was obtained within 48 hours prior to randomization. Indwelling bladder catheters were required to be removed or replaced, unless considered unsafe or contraindicated, before or within 24 hours after randomization.

The applicant stated that the primary endpoint of the ZEUS Study was to demonstrate that CONTEPO™ was non-inferior to PIP–TAZ in overall success based on clinical cure (complete resolution or significant improvement of signs and symptoms such that no further antimicrobial therapy is warranted) and microbiologic eradication (baseline pathogen was reduced to $<10^4$ CFU/mL on urine culture and if applicable, negative on repeat blood culture) in the microbiologic modified intent-to-treat

(m-MITT) population at the test-of-cure visit (TOC), which occurred on the 19th to 21st day after completion of a fixed 7 days of treatment with the study drug, or up to 14 days of treatment for patients diagnosed with concurrent bacteremia to comply with current treatment guidelines in these patients.

Patients with any missing or presumed eradications post-baseline urine sample were classified as indeterminates, and conservatively deemed as failures in overall success analysis.[77] [78] The applicant also reported that the study had two secondary endpoints. Secondary objectives were to compare: (1) Clinical cure rates in the two treatment groups in the MITT, m-MITT, Clinical Evaluable (CE), and Microbiologic Evaluable (ME) populations at TOC, and (2) microbiological eradication rates in m-MITT and ME populations at TOC.

The applicant also included evidence from a post-hoc study wherein all pathogens isolated from patients who had a baseline and TOC pathogen underwent blinded, post-hoc, pulsed-field gel electrophoresis (PFGE) molecular typing analysis. Microbiologic outcome was also defined utilizing the PFGE results, whereby microbiologic persistence required the same genus and species of baseline and post-baseline pathogens, as well as PFGE-confirmed genetic identity.

The applicant stated that the ZEUS Study met its primary objective of showing non-inferiority of CONTEPO™ compared to PIP–TAZ with overall success rates (that is, clinical cure and microbiological eradication of baseline pathogen) of 64.7 percent (119/184 CONTEPO™ patients) versus 54.5 percent (97/178 PIP–TAZ patients) in the m-MITT population at TOC (treatment difference 10.2 percent, 95 percent CI: −0.4, 20.8). We note that, based on the 95 percent confidence interval reported at the primary endpoint, CONTEPO™'s success rates were not found to be different from PIP–TAZ in a statistically significant manner. The applicant reports that the identity and frequency of pathogens recovered at baseline from patients in the ZEUS Study were similar in both the CONTEPO™ and PIP–TAZ treatment groups. The most common pathogens identified were Enterobacteriaceae, identified in 96.2 percent of the CONTEPO™ patients and 94.9 percent of the PIP–TAZ patients, including *E. coli,* identified in 72.3 percent of the CONTEPO™ patients and 74.7 percent of the PIP–TAZ patients; *K. pneumoniae,* identified in 14.7 percent of the CONTEPO™ patients and 14.0 percent of the PIP–TAZ patients; Enterobacter cloacae species complex, identified in 4.9 percent of the CONTEPO™ patients and 1.7 percent of the PIP–TAZ patients; and *Proteus mirabilis,* identified in 4.9 percent of the CONTEPO™ patients and 2.8 percent of the PIP–TAZ patients. Gram-negative aerobes other than Enterobacteriaceae included *Pseudomonas aeruginosa,* which was identified in 4.3 percent of the CONTEPO™ patients and 5.1 percent of the PIP–TAZ patients, and *Acinetobacter baumannii-calcoaceticus* species complex, identified in 1.1 percent of the CONTEPO™ patients and none of the PIP–TAZ patients. The applicant indicated that these pathogens are representative of the pathogens that have been recovered in other studies of patients who have been diagnosed with a cUTI or AP.

In terms of secondary endpoints, the applicant stated that clinical cure rates were greater than 90 percent in both treatment groups at TOC in the MITT, m-MITT, CE, and ME analysis groups. In addition to the findings discussed above, with the post-hoc analysis adjusting for PFGE results in both treatment arms, CONTEPO™ demonstrated a 10.5 percent treatment difference compared to PIP–TAZ with a microbiological response rate of 70.7 percent versus 60.1 percent, respectively, in the m-MITT population at TOC (95 percent CI: 0.2, 20.8). The applicant indicated that by specifying the genus and species of the bacteria present at the start of treatment, the post-hoc PFGE analysis shows that when measuring microbiological eradication rates CONTEPO™ demonstrated a positive difference significant at the 95 percent confidence level.[79]

With respect to safety, the applicant reports that in the ZEUS Study a total of 42.1 percent of the CONTEPO™ patients and 32.0 percent of the PIP–TAZ patients experienced at least one treatment-emergent adverse event, or TEAE. Most TEAEs were mild or moderate in severity, and severe TEAEs were uncommon (2.1 percent of the CONTEPO™ patients and 1.7 percent of the PIP–TAZ patients). The most common TEAEs in both treatment groups were transient, asymptomatic laboratory abnormalities and gastrointestinal events. Treatment-emergent serious adverse events, or SAEs, were uncommon in both treatment groups. There were no deaths in the study and one SAE in each treatment group was deemed related to the study drug (hypokalemia in a CONTEPO™ patient and renal impairment in a PIP–TAZ patient), leading to study drug discontinuation in the PIP–TAZ patient. Study drug discontinuations due to TEAEs were infrequent and similar between treatment groups (3.0 percent of CONTEPO™ patients and 2.6 percent of PIP–TAZ patients). The applicant further stated that the most common laboratory abnormality TEAEs were increases in the levels of alanine aminotransferase (8.6 percent of CONTEPO™ patients and 2.6 percent of PIP–TAZ patients) and aspartate transaminase (7.3 percent of CONTEPO™ patients and 2.6 percent of PIP–TAZ patients). None of the aminotransferase elevations were symptomatic or treatment-limiting, and none of the patients met the criteria for Hy's Law (a method of assessing a patient's risk of fatal drug-induced liver injury). Outside of the United States, elevated liver aminotransferases are listed among undesirable effects in labeling for the use of IV fosfomycin. Finally, the applicant stated that hypokalemia occurred in 71 of the 232 (30.6 percent) CONTEPO™ patients and 29 of the 230 (12.6 percent) PIP–TAZ patients. Most decreases in potassium levels were mild to moderate in severity. Shifts in potassium levels from normal at baseline to hypokalemia, as determined by worst post-baseline hypokalemia values, were more frequent in the patients in the CONTEPO™ group than the patients in the PIP–TAZ group for mild (17.7 percent compared to 11.3 percent), moderate (11.2 percent compared to 0.9 percent), and severe (1.7 percent compared to 0.4 percent) categories of hypokalemia. Hypokalemia was deemed a TEAE in 6.4 percent of the patients receiving CONTEPO™ and 1.3 percent of the patients receiving PIP–TAZ, and all cases were transient and asymptomatic. The applicant noted that post-baseline QT intervals calculated using Fridericia's formula, or QTcF, of greater than 450 to less than

[77] Eckburg, et al., ''Phenotypic Antibiotic Resistance in ZEUS: Multi-center, Randomized, Double-Blind Phase II/III Study of ZTI–01 versus Piperacillin-Tazobactam (P–T) in the Treatment of Patients with Complicated Urinary Tract Infections (cUTI) including Acute Pyelonephritis (AP) Poster,'' 2017.

[78] Kaye, et al., ''Intravenous Fosfomycin (ZTI–01) for the Treatment of Complicated Urinary Tract Infections (cUTI) including Acute Pyelonephritis (AP): Results from a Multi-center, Randomized, Double-Blind Phase II/III Study in Hospitalized Adults (ZEUS),'' 2017.

[79] Skarinsky, et al., ''Per Pathogen Outcomes from the ZEUS study, a Multi-center, Randomized, Double-Blind Phase II/III Study of ZTI–01 (fosfomycin for injection) versus Piperacillin-Tazobactam (P–T) in the Treatment of Patients with Complicated Urinary Tract Infections (cUTI) including Acute Pyelonephritis (AP),'' 2017.

or equal to 480 msec (baseline QTcF of less than or equal to 450 msec) occurred at a higher frequency in CONTEPO™ patients (7.3 percent) compared to PIP–TAZ patients (2.5 percent). In the CONTEPO™ arm, these results appear to be associated with the hypokalemia associated with the salt load of the IV formulation. Only 1 patient in the PIP–TAZ group had a baseline QTcF of less than or equal to 500 msec and a post-baseline QTcF of greater than 500 msec.

In addition to the assertions of clinical improvement based on its pivotal study, the applicant stated that CONTEPO™ provides a broad spectrum of *in vitro* activity against a variety of clinically important MDR Gram-negative pathogens, including ESBL-producing Enterobacteriaceae, CRE, and Gram-positive pathogens, including methicillin-resistant *Staphylococcus aureus,* or MRSA, and vancomycin-resistant enterococci.[80] [81] [82] [83] The applicant also believes that CONTEPO™, due to its unique mechanism of action, has demonstrated synergistic or additive activity in *in vitro* studies when used in combination with other antibiotic classes in preclinical studies.[84] [85] [86] The applicant further stated that the use of CONTEPO™ has the potential to spare the use of carbapenems and other last-line therapies and, thereby, has the potential to reduce the development of resistance to existing antibiotic classes.[87] Additionally, the applicant believes that the use of CONTEPO™ has the potential to reduce patients' hospital lengths of stay and patient morbidity due to the ability to provide early appropriate therapy in patients who have been diagnosed with suspected or confirmed MDR pathogens.[88] [89] The applicant also stated that the submitted literature provides cases wherein the use of CONTEPO™ could provide an important treatment option for patients who have been diagnosed with infections caused by pathogens resistant to all other available IV antibiotics.[90] [91] Finally, the applicant asserted that the use of CONTEPO™ has immunomodulating activities that potentially may improve outcomes for serious infections,[92] and may protect against gentamicin induced nephrotoxicity.[93]

We have several concerns regarding whether CONTEPO™ meets the substantial clinical improvement criterion. First, we are concerned that we are unable to identify if any of the patients enrolled in the ZEUS Study were from the United States. As we have noted in previous rulemaking (83 FR 41309), given the geographic variability of antibiotic resistance, we are unsure to what extent results from studies utilizing an international cohort of patients generate inferences that are applicable to the U.S. context and, in particular, to the Medicare-eligible population.

Second, we are unsure if PIP–TAZ is the only proper comparator for CONTEPO™, or if other treatments should have been considered as well. There are a number of additional antimicrobials with similar indications that are available for patients who have been diagnosed with cUTIs. Such treatments might include meropenem-vaborbactam or plazomicin. Prior studies include a meta-analysis of 10 studies (7 randomized) comparing the clinical efficacy of IV fosfomycin against other antibiotics including sulbenicillin, sulbactam/cefoperazone, cefotaxime, fosfomycin/colistin, and minocycline/cefuzonam. This meta-analysis did not observe a difference in clinical efficacy between fosfomycin and respective comparators (odds ratio (OR) 1.44, 95 percent CI (0.96, 2.15)) irrespective of monotherapy (OR 1.41, 95 percent CI (0.83, 2.39)) or combination therapy (OR 1.48, 95 percent CI (0.81, 2.71.)). The same results were obtained when studies with poor quality were excluded (OR 1.45, 95 percent CI (0.94, 2.24)).[94]

Third, we have two methodological concerns regarding the applicant's assertions based on the ZEUS Study. There does not appear to be any statistical comparison of the patients in each arm in terms of demographics and, therefore, it is difficult to assess whether the two intervention arms are balanced as the applicant inferred. We acknowledge that use of a double-blinded, randomized study design (which was used in the ZEUS Study) should minimize bias and control for unmeasured variables between treatment arms. However, we are concerned about a lack of detail on the different dropout rates of patients within each arm of the ZEUS Study, including data on causes and treatment of patients that dropped out and any bias that might introduce. We also are concerned that the ZEUS Study did not demonstrate a superior clinical outcome with statistical significance in its primary endpoint. Rather, the applicant is asserting the technology represents a substantial clinical improvement on the basis of meeting a secondary endpoint, the cure rates based on additional PFGE analysis. In addition, we are concerned that the use of m-MITT, rather than ITT, may have biased the results upwards by focusing on a subset of the treatment group, rather than the entire random sample.[95]

Finally, we are concerned that many of the assertions the applicant has made regarding the efficacy of CONTEPO™ on MDR gram-negative pathogens and broader public health benefits come from *in vitro* studies or may be speculative in nature. It may be helpful

[80] Flamm, R., et al., ''Activity of fosfomycin when tested against US contemporary bacterial isolates,'' *Diagnostic Microbiology and Infectious Disease,* 2018.

[81] Mendes, R.E., et al., ''Molecular Characterization of Clinical Trial Isolates Exhibiting Increased MIC Results during Fosfomycin (ZTI–01) Treatment in a Phase II/III Clinical Trial for Complicated Urinary Tract Infections (ZEUS),'' 2018.

[82] Rhomberg, P., et al., ''Evaluation of Fosfomycin Activity When Combined with Selected Antimicrobial Agents and Tested against Bacterial Isolates Using Checkerboard Methods,'' 2017.

[83] Falagas, M., et al., ''Antimicrobial susceptibility of multidrug-resistant (MDR) and extensively drug-resistant (XDR) Enterobacteriaceae isolates to fosfomycin,'' *International Journal of Antimicrobial Agents*, 2010.

[84] Flamm, R., et al., ''Time Kill Analyses of Concerning Gram-Negative Bacteria with Fosfomycin Alone and in Combination with Select Antimicrobial Agents,'' 2017.

[85] Avery & Nicolau, ''In Vitro Synergy of Fosfomycin and Parenteral Antimicrobials Against Carbapenem-Nonsusceptible Pseudomonas aeruginosa,'' 2018.

[86] Albiero, J., et al., ''Pharmacodynamic Evaluation of the Potential Clinical Utility of Fosfomycin and Meropenem in Combination Therapy against KPC–2-Producing Klebsiella pneumonia,'' *Antimicrobial Agents and Chemotherapy,* 2016.

[87] Hayden, M.K. & Won, S.Y., ''Carbapenem-Sparing Therapy for Extended-Spectrum β-Lactamase–Producing *E coli* and *Klebsiella pneumoniae* Bloodstream Infection,'' *JAMA,* 2018.

[88] Mocarski, et al., ''Economic Burden Associated with Key Gram-negative Pathogens among Patients with Complicated Urinary Tract Infections across US Hospitals,'' 2014.

[89] Lodise, et al., ''Carbapenem-resistant Enterobacteriaceae (CRE) or Delayed Appropriate Therapy (DAT)—Does One Affect Outcomes More Than the Other Among Patients With Serious Infections Due to Enterobacteriaceae?,'' 2017.

[90] Chen, L., et al., ''Pan-Resistant New Delhi Metallo-Beta-Lactamase-Producing *Klebsiella pneumonia*—Washoe County, Nevada, 2016,'' 2017.

[91] Rios, P., et al., ''Extensively drug-resistant (XDR) *Pseudomonas aeruginosa* identified in Lima, Peru co-expressing a VIM–2 metallo-blactamase, OXA–1 b-lactamase and GES–1 extended-spectrum b-lactamase,'' *JMM Case Reports,* 2018.

[92] Zeitlinger, et al., ''Immunomodulatory effects of fosfomycin in an endotoxin model in human blood.'' *Journal of Antimicrobial Chemotherapy,* 2007.

[93] Yanagida, et al., ''Protective effect of fosfomycin on gentamicin-induced lipid peroxidation of rat renal tissue,'' *Chem Biol Interact,* 2004.

[94] Grabien, et al., ''Intravenous fosfomycin—Back to the Future; Systematic Review and Meta-analysis of the Clinical Literature,'' *Clinical Microbiology and Infection,* 2017.

[95] Beckett, R.D., Loeser, K.C., Bowman, K.R., Towne, T.G., ''Intention-to-treat and transparency of related practices in randomized, controlled trials of anti-infectives,'' *BMC Med Res Methodol,* 2016, vol. 16(1), pp. 106, Published August 24, 2016, doi:10.1186/s12874–016–0215–2.

to have further evidence, particularly prospectively collected and tested clinical data, to support the assertions that the use of CONTEPO™ reduces hospital lengths of stay and patient morbidity, and enhances antibiotic stewardship.

We are inviting public comments on whether CONTEPO™ meets the substantial clinical improvement criterion.

Below we summarize and respond to a written public comment received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for CONTEPO™.

Comment: In response to a question presented at the New Technology Town Hall meeting, the applicant explained why the post-hoc reanalysis of the primary endpoint (overall success, a composite of clinical cure and microbiologic eradication) from the ZEUS Study using pulse-field gel electrophoresis, which the applicant asserted demonstrated a statistically significant difference between CONTEPO™ and PIP–TAZ, is clinically important. The applicant stated that the post-hoc analysis was able to differentiate the patients who had eradication of the identified and treated baseline pathogen from those patients who developed or were likely to develop another infection from a newly acquired pathogen (different strain) following the ~2-week period between the end of IV therapy and the test-of-cure evaluation. However, the applicant indicated that there are many reasons why patients may acquire another pathogen and/or develop new infections after completing IV therapy, including indwelling urinary catheters or instrumentation (for example, nephrostomy tubes, ureteric stents, etc.) or anatomical abnormalities. The applicant stated that because of these confounding factors, the PFGE reanalysis allowed for the differentiation of the true persistence of the same pathogen that was present at baseline from a different pathogen that might look the same, but was clearly genetically distinct.

Response: We appreciate the applicant's further explanation of the PFGE analysis. We will take this information into consideration when deciding whether to approve new technology add-on payments for CONTEPO™.

e. DuraGraft® Vascular Conduit Solution

Somahlution, Inc. submitted an application for new technology add-on payments for DuraGraft® for FY 2020. (We note that the applicant previously submitted applications for new technology add-on payments for DuraGraft® for FY 2018 and FY 2019, which were withdrawn.) According to the applicant, DuraGraft® is designed to protect the endothelium of the vein graft by mitigating ischemic reperfusion injury (IRI), the basis of vein graft disease (VGD) and vein graft failure (VGF), both of which are intimately linked to graft and patient outcomes.[96] [97] [98] According to the applicant, specific VGD and VGF clinical outcomes affected by the use of DuraGraft® include reductions in myocardial infarction (MI), repeat revascularization and major adverse cardiovascular events (MACE). The applicant stated that DuraGraft® is a preservation solution, not a storage solution, used during standard graft handling, flushing, and bathing steps.

The applicant indicated that vein graft endothelial damage is the principal mediator of VGD following grafting in bypass surgeries.[99] [100] According to the applicant, the endothelium can be destroyed or damaged intraoperatively through the acute physical stress of harvesting, storage, and handling, and through more insidious processes such as those associated with ischemic injury, metabolic stress and oxidative damage. The applicant also noted that vein graft solutions can independently damage the endothelium during the harvesting and storage stages prior to vein grafting. The applicant also referred to more recent information to depict that damage associated with the use of graft storage solutions has the highest correlation with the development of 12-month VGF following coronary artery bypass grafting (CABG).[101] More specifically regarding vein graft solutions, the applicant asserted that there are two processes associated with current vein graft solutions that lead to IRI and ultimately VGD: (1) Current vein graft solutions cause ''solution damage;'' and (2) current vein graft solutions do not protect against IRI, the basis for VGD.[102] [103] [104] [105] [106] [107] [108] According to the applicant, current vein graft solutions are used to flush and store vascular grafts during the ex vivo ischemic interval of the surgical procedure. However, these solutions do not protect the graft from ischemia reperfusion injury and have no preservation ability. Further, the applicant asserted that some of the solutions are incompatible with graft tissue resulting in ischemic damage that is compounded by ''solution damage''.[109] [110] [111]

The applicant explained that there are two mechanisms leading to VGD: (1) Endothelial damage associated with the

[96] Salvadori, M., Rosso, G., and Bertoni, E., ''Update on Ischemia-reperfusion Injury in Kidney Transplantation: Pathogenesis and Treatment,'' World Transplant, June 24, 2015, vol. 5(2), pp. 52–67.

[97] Osgood, M.J., Hocking, K.M., Voskresensky, I.V., et al., ''Surgical vein graft preparation promotes cellular dysfunction, oxidative stress, and intimal hyperplasia in human saphenous vein,'' *J Vasc Surg,* 2014, vol. 60, pp. 202–211.

[98] Shuhaiber, J.H., Evans, A.N., Massad, M.G., and Geha, A.S., ''Mechanisms and Future Directions for Prevention of Vein Graft Failure in Coronary Bypass Surgery,'' *European Journal of Cardio-Thoracic Surgery,* vol. 22, Issue 3, September 1, 2002, pp. 387–396.

[99] Harskamp, R.E., Alexander, J.H., Schulte, P.J., Brophy, C.M., Mack, M.J., Peterson, E.D., Williams, J.B., Gibson, C.M., Califf, R.M., Kouchoukos, N.T., Harrington, R.A., Ferguson, Jr., T.B., Lopes, R.D., ''Vein Graft Preservation Solutions, Patency, and Outcomes After Coronary Artery Bypass Graft Surgery Follow-up From PREVENT IV Randomized Clinical Trial,'' *JAMA Surg.,* 2014, vol. 149(8), pp. 798–805.

[100] Testa, L., Bedogni, F., ''Treatment of Saphenous Vein Graft Disease: Never Ending Story of the Eternal Return,'' *Res Cardiovasc Med.,* 2014, vol. 3(3), e21092.

[101] Ibid.

[102] Shinjo, H., et al., ''Effect of irrigation solutions for arthroscopic surgery on intraarticular tissue: comparison in human meniscus-derived primary cell culture between lactate Ringer's solution and saline solution,'' *Journal of Orthopaedic Research,* 2002, vol. 20, pp. 1305–1310.

[103] Breborowicz, A. and Oreopoulos, D.G., ''Is normal saline harmful to the peritoneum?'', Perit Dial Int., 2005 Apr; 25 Suppl 4:S67–70.

[104] Pusztaszeri, M.P., Seelentag, Walter, Bosman, F.T., ''Immunohistochemical Expression of Endothelial Markers CD31, CD34, von Willebrand Factor, and Fli-1 in Normal Human Tissues,'' *Journal of Histochemistry & Cytochemistry,* 2006, vol. 54(4), pp. 385–395.

[105] Polubinska, A., et al., ''Normal Saline induces oxidative stress in peritoneal mesoyhelial cells,'' *Journel of Pediatric Surgery,* 2008, vol. 43, pp. 1821–1826.

[106] Sengupta, S., Prabhat, K., Gupta, V., Vij, H., Vij, R., Sharma, V., ''Artefacts Produced by Normal Saline When Used as a Holding Solution for Biopsy Tissues in Transit,'' *J. Maxillofac. Oral Surg.,* (Apr–June 2014), vol. 13(2), pp. 148–151.

[107] Wilbring, M., Tugtekin, S.M., Zatschler, B., Ebner, A., Reichenspurner, H., Matschke, K., Deussen, A., ''Even short-time storage in physiological saline solution impairs endothelial vascular function of saphenous vein grafts,'' *Eur J Cardiothorac Surg.,* 2011 Oct, vol. 40(4), pp. 811–815.

[108] Weiss, D.R., et al., ''Extensive deendothelialization and thrombogenicity in routinely prepared vein grafts for coronary bypass operations: facts and remedy,'' *Int J Clin Exp Med,* 2009, vol. 2, pp. 95–113.

[109] Weiss, D.R., et al., ''Extensive deendothelialization and thrombogenicity in routinely prepared vein grafts for coronary bypass operations: facts and remedy,'' *Int J Clin Exp Med,* 2009, vol. 2, pp. 95–113.

[110] Ibid.

[111] Thatte, H.S., Biswas, K.S., Najjar, S.F., Birjiniuk, V., Crittenden, M.D., Michel, T., and Khuri, S.F., ''Multi-Photon Microscopic valuation of Saphenous Vein Endothelium and Its Preservation With a New Solution, GALA,'' *Annals Thoracic Surgery,* 2003, vol. 75, pp. 1145–52.

harvesting and storage processes; and (2) VGD pathophysiological changes that occur in damaged vein grafts following reperfusion at the time of graft anastomosis. According to the applicant, these changes are apparent within minutes to hours of grafting and are manifested as endothelial dysfunction, death and/or denudation and include pro-inflammatory, pro-thrombogenic and aberrant proliferative changes within the graft. The applicant further characterized these changes as initial endothelial reperfusion phase responses, which set in motion a damage-response domino-like effect thereby perpetuating a cycle of prolonged reperfusion phase injury with subsequent VGD.

The applicant further noted that endothelial dysfunction and inflammation results not only in the diminished ability of the graft to respond appropriately to new blood flow patterns, but also may thwart positive adaptive vein graft remodeling. According to the applicant, this is because proper vein graft remodeling is dependent upon a functional endothelial response to shear stress that involves the production of remodeling factors by the endothelium including nitro vasodilators, prostaglandins, lipoxyoxygenases, hyperpolarizing factors and other growth factors.[112] Therefore, damaged, missing and/or dysfunctional endothelial cells prevent graft adaption, which makes the graft susceptible to shear mediated endothelial damage. The applicant explained that the collective damage results in intimal hyperplasia or graft wall thickening that is the basis for atheroma development, stenosis and subsequent lumen narrowing leading to the end state of VGD, VGF.[113] The applicant also noted that the pathologic changes leading to VGD, occlusion and loss of vasomotor function, are well documented.[114] [115] [116] [117] [118] [119] [120] Presenting an intact functional endothelial layer at the time of grafting is, therefore, critical to protecting the graft and its associated endothelium from damage that occurs post-grafting, in turn conferring protection against graft failure.[121] The applicant stated that given the low success rate of VGF intervention after surgery (for example, percutaneous coronary intervention and saphenous vein graft intervention [122]), addressing graft endothelial protection at the time of surgery is critical.

With respect to the newness criterion, DuraGraft® has not received FDA approval as of the time of the development of this proposed rule. The applicant indicated that it anticipates FDA approval of its premarket application by July 1, 2019. The applicant also indicated that ICD–10–PCS code XY0VX83 (Extracorporeal introduction of endothelial damage inhibitor to vein graft, New Technology Group 3) would identify procedures involving the use of the DuraGraft® technology.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would, therefore, not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, there are currently no other treatment options available with the same mechanism of action as that of DuraGraft®. According to the applicant, the currently available vein graft solutions, which consist of saline, buffered saline, blood, and electrolyte solutions, are not preservation solutions but ''storage'' solutions that do not protect the graft vascular endothelium nor mitigate IRI, the basis of VGD.[123] [124] [125] [126] The applicant stated that these solutions are used merely to keep grafts wet from the time they are harvested until the time they are used in CABG. According to the applicant, exposure of saphenous vein grafts to these solutions has been shown to cause significant damage to the graft within minutes.[127] [128] [129] [130]

The applicant explained that DuraGraft® is a formulated ''preservation'' solution that can be used during handling, flushing, and bathing steps without changing standard surgical practice. According to the applicant, the handling step includes using an atraumatic surgical technique, avoiding over pressurization and checking for leakage, excessive handling and distortion. The applicant further noted that vascular segments (that become vascular grafts) are comprised of a number of different cell types that function together in an integrated manner post-grafting and, therefore, protection of all cell types during graft flushing and storage is critical for maintenance of graft viability and normal graft functioning.

The applicant indicated that DuraGraft® separates itself from current vein graft solutions through its unique

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[116] Sellke, F.W., Boyle, E.M., Verrier, E.D., ''The pathophysiology of vasomotor dysfunction,'' *Ann Thorac Surg,* 1996, vol. 64, pp. S9–S15.

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[122] Testa, L., Bedogni, F., ''Treatment of Saphenous Vein Graft Disease: Never Ending Story of the Eternal Return,'' *Res Cardiovasc Med.,* 2014, vol. 3(3), e21092.

[123] Salvadori, M., Rosso, G., and Bertoni, E., ''Update on Ischemia-reperfusion Injury in Kidney Transplantation: Pathogenesis and Treatment,'' World Transplant, June 24, 2015, vol. 5(2), pp. 52–67.

[124] Lee, J.C. and Christie, J.D., ''Primary Graft Dysfunction,'' *Proc Am Thorac Soc.,* 2009, vol. 6, pp 39–46.

[125] Osgood, M.J., Hocking, K.M., Voskresensky, I.V., et al., ''Surgical vein graft preparation promotes cellular dysfunction, oxidative stress, and intimal hyperplasia in human saphenous vein,'' *J Vasc Surg,* 2014, vol. 60, pp. 202–211.

[126] Shuhaiber, J.H., Evans, A.N., Massad, M.G., and Geha, A.S., ''Mechanisms and Future Directions for Prevention of Vein Graft Failure in Coronary Bypass Surgery,'' *European Journal of Cardio-Thoracic Surgery,* vol. 22, Issue 3, September 1, 2002, pp. 387–396.

[127] Weiss, D.R., et al., ''Extensive deendothelialization and thrombogenicity in routinely prepared vein grafts for coronary bypass operations: facts and remedy,'' *Int J Clin Exp Med,* 2009, vol. 2, pp. 95–113.

[128] Wilbring, M., Tugtekin, S.M., Zatschler, B., Ebner, A., Reichenspurner, H., Matschke, K., Deussen, A., ''Even short-time storage in physiological saline solution impairs endothelial vascular function of saphenous vein grafts,'' *Eur J Cardiothorac Surg.,* 2011 Oct, vol. 40(4), pp. 811–815.

[129] Tsakok, M., Montgomery-Taylor, S. and Tsakok, T., ''Storage of saphenous vein grafts prior to coronary artery bypass grafting: is autologous whole blood more effective than saline in preserving graft function?'' *Inter Cardiovasc Thorac Surg,* 2012, vol. 15, pp. 720–25.

[130] Thatte, H.S., Biswas, K.S., Najjar S.F., Birjiniuk, V., Crittenden, M.D., Michel, T., and Khuri, S.F., ''Multi-Photon Microscopic valuation of Saphenous Vein Endothelium and Its Preservation With a New Solution, GALA.'' *Annals Thoracic Surgery,* 2003, vol. 75, pp. 1145–52.

composition of ingredients, a physiologic saline solution that combines free radical scavengers and antioxidants (glutathione, ascorbic acid) and nitric oxide synthase substrate (L-arginine), as discussed later in this section. According to a summary of ex vivo performance data and studies provided by the applicant, the use of DuraGraft® has been shown to preserve vascular graft viability, as well as graft functional and structural integrity during ex vivo storage and flushing.[131] [132] [133] The applicant noted that these studies evaluated graft cellular viability and structural integrity and assessed molecular and biochemical markers of normal endothelial functioning. Specifically, endothelial and smooth muscle cells were assessed.

All veins used in these studies were collected from patients undergoing cardiac bypass surgery at the Boston VA or Saint Joseph's Hospital of Atlanta. Veins were harvested using the ''Open Saphenous Vein Harvest'' (OSVH) technique.[134] [135] [136] Segments of the collected veins not being used for the bypass surgery were used for the performance bench studies.

According to the applicant, viability studies conducted in conjunction with multi-photon microscopy demonstrated a protective effect from the use of DuraGraft® on vascular endothelial viability and graft structural integrity for storage times of up to 5 hours at room temperature (21 °C).[137] The applicant also stated that, conversely, vascular segments were not able to be maintained in a viable condition when stored for as short a time as 15 minutes in standard-of-care solutions consistent with what has been published by others. According to the applicant, DuraGraft® demonstrated its ability to preserve the viability, structure and function of endothelium in radial and internal mammary arteries, as well as saphenous veins for extended periods.[138]

According to the information submitted by the applicant, the ingredients found in DuraGraft® play a primary role in DuraGraft® exhibiting a different mechanism of action from other solutions that are commonly used to treat the same disease process and patient population. According to the study cited by the applicant, the rapid loss of endothelial cell structural and functional integrity in saphenous veins stored in standard storage solutions can be avoided by incorporating a physiologic saline solution that combines free radical scavengers and antioxidants (glutathione, ascorbic acid) and nitric oxide synthase substrate (L-arginine) providing a favorable environment and cellular support during ex vivo storage.[139] The same study also indicated that these three ingredients were chosen because of their putative effect on endothelial cell function and that their use may act synergistically to enhance the cell preservation properties of the solution. The authors of the study asserted that glutathione increases L-arginine transport in endothelial cells and may lead to the formation of biologically active S-nitrosoglutathione and to the stimulation of endothelial nitric oxide synthase (eNOS) activity, nitric oxide generation, and coronary vasodilatation. According to the authors, ascorbic acid also increases eNOS activity by preserving endothelium-derived nitric oxide bioactivity by possibly scavenging superoxide anions and preventing oxidative destruction of tetrahydrobiopterin, an eNOS cofactor. Furthermore, according to the study, the presence of ascorbic acid in a physiologic saline solution may prevent the oxidation of this eNOS cofactor during vessel storage and help maintain eNOS function and nitric oxide generation in vascular endothelium. The study authors also noted that ascorbic acid, by its reducing property, may assist sustained long-term release of nitric oxide from these compounds in vessels preserved in a physiologic saline solution and, therefore, help maintain the patency and tone of the vessels during storage. Additionally, according to the authors of the study, ascorbic acid mediated reversal of endothelial dysfunction, reduced platelet activation and leukocyte adhesion, inhibited smooth muscle cell proliferation and lipid peroxidation, and increased prostacyclin production which have been demonstrated in numerous cardiovascular pathologies. Finally, the authors stated that L-arginine is a known substrate of nitric oxide synthase and has been shown to decrease neutrophil-endothelial cell interactions in inflamed vessels.[140]

Regarding the second criterion, whether a product is assigned to the same or different MS–DRG, according to the applicant, cases involving patients who may be eligible to receive treatment involving DuraGraft® would be assigned to the same MS–DRGs as patients who received treatment involving heparinized blood, saline, and electrolyte solutions.

Regarding the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant indicated that heparinized blood, saline and electrolyte solutions involve treatment of the same disease process and the same patient population as DuraGraft®.

Based on the applicant's statements presented above, we are concerned that the mechanism of action of DuraGraft® may be the same or similar to other vein graft storage solutions. Specifically, we are concerned that current solutions used in vein graft surgical procedures may be similar to DuraGraft® in composition and treatment indication and, therefore, have the same or similar mechanism of action. We are inviting public comments on whether the DuraGraft® meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. In order to identify the range of MS–DRGs that cases representing potential patients who may be eligible for treatment using DuraGraft® may map to, the applicant identified all MS–DRGs for patients who underwent CABG. Specifically, the applicant searched the FY 2017 MedPAR file for Medicare fee-for-service inpatient hospital claims submitted between October 1, 2016 and September 30, 2017, and identified potential cases that may be eligible for treatment using DuraGraft® by the following ICD–10–PCS procedure codes:

[131] Thatte, H.S., Biswas, K.S., Najjar S.F., Birjiniuk, V., Crittenden, M.D., Michel, T., and Khuri, S.F., ''Multi-Photon Microscopic valuation of Saphenous Vein Endothelium and Its Preservation With a New Solution, GALA.'' *Annals Thoracic Surgery,* 2003, vol. 75, pp. 1145–52.

[132] Hussaini, B.E., Lu, X.G., Wolfe, A., Thatte, H.S., ''Evaluation of Endoscopic Vein extraction on Structural and Functional Viability of Saphenous Vein Endothelium,'' *J Cardothorac Surg,* 2011, vol. 6, pp. 82–89.

[133] Rousou, L.J., Taylor, K.B., Lu, X.G., et al., ''Saphenous vein conduits harvested by endoscopic technique exhibit structural and functional damage,'' *Ann Thorac Surg,* 2009, vol. 87, pp. 62–70.

[134] Ibid.

[135] Hussaini, B.E., Lu, X.G., Wolfe, A., Thatte, H.S., ''Evaluation of Endoscopic Vein extraction on Structural and Functional Viability of Saphenous Vein Endothelium,'' *J Cardothorac Surg,* 2011, vol. 6, vol. 82–89.

[136] Thatte, H.S., Biswas, K.S., Najjar, S.F., Birjiniuk, V., Crittenden, M.D., Michel, T., and Khuri, S.F., ''Multi-Photon Microscopic valuation of Saphenous Vein Endothelium and Its Preservation With a New Solution, GALA.'' *Annals Thoracic Surgery,* 2003, vol. 75, pp. 1145–52.

[137] Ibid.

[138] Ibid.

[139] Thatte, H.S., Biswas, K.S., Najjar, S.F., Birjiniuk, V., Crittenden, M.D., Michel, T., and Khuri, S.F., ''Multi-Photon Microscopic valuation of Saphenous Vein Endothelium and Its Preservation With a New Solution, GALA.'' *Annals Thoracic Surgery,* 2003, vol. 75, pp. 1145–52.

[140] Ibid.

ICD–10–PCS procedure code	Code description
021009W	Bypass coronary artery, one artery from aorta with autologous venous tissue, open approach.
02100AW	Bypass coronary artery, one artery from aorta with autologous arterial tissue, open approach.
021049W	Bypass coronary artery, one artery from aorta with autologous venous tissue, percutaneous endoscopic approach.
02104AW	Bypass coronary artery, one artery from aorta with autologous arterial tissue, percutaneous endoscopic approach.
021109W	Bypass coronary artery, two arteries from aorta with autologous venous tissue, open approach.
02110AW	Bypass coronary artery, two arteries from aorta with autologous arterial tissue, open approach.
021149W	Bypass coronary artery, two arteries from aorta with autologous venous tissue, percutaneous endoscopic approach.
02114AW	Bypass coronary artery, two arteries from aorta with autologous arterial tissue, percutaneous endoscopic approach.
021209W	Bypass coronary artery, three arteries from aorta with autologous venous tissue, open approach.
02120AW	Bypass coronary artery, three arteries from aorta with autologous arterial tissue, open approach.
021249W	Bypass coronary artery, three arteries from aorta with autologous venous tissue, percutaneous endoscopic approach.
02124AW	Bypass coronary artery, three arteries from aorta with autologous arterial tissue, percutaneous endoscopic approach.
021309W	Bypass coronary artery, four or more arteries from aorta with autologous venous tissue, open approach.
02130AW	Bypass coronary artery, four or more arteries from aorta with autologous arterial tissue, open approach.
021349W	Bypass coronary artery, four or more arteries from aorta with autologous venous tissue, percutaneous endoscopic approach.
02134AW	Bypass coronary artery, four or more arteries from aorta with autologous arterial tissue, percutaneous endoscopic approach.

This resulted in potential eligible cases spanning 100 MS–DRGs, with approximately 93 percent of all of these potential cases, 66,553, mapping to the following 10 MS–DRGs:

MS–DRG	MS–DRG title
MS–DRG 003	Extracorporeal Membrane Oxygenation (ECMO) or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth & Neck with Major Operating Room Procedure.
MS–DRG 216	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC.
MS–DRG 219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC.
MS–DRG 220	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC.
MS–DRG 228	Other Cardiothoracic Procedures with MCC.
MS–DRG 229	Other Cardiothoracic Procedures without CC.
MS–DRG 233	Coronary Bypass with Cardiac Catheterization with MCC.
MS–DRG 234	Coronary Bypass with Cardiac Catheterization without MCC.
MS–DRG 235	Coronary Bypass without Cardiac Catheterization with MCC.
MS–DRG 236	Coronary Bypass without Cardiac Catheterization without MCC.

Using the 66,553 identified cases, the average case-weighted unstandardized charge per case was $212,885. The applicant then standardized the charges. The applicant did not remove charges for any current treatment because the applicant indicated that there are no other current treatment options available. The applicant noted that it did not provide an inflation factor to project future charges. The applicant added $2,751 in charges for the costs of the DuraGraft® technology. This charge was created by assuming the DuraGraft® technology will cost $850 per unit as estimated by the applicant, and by applying the national average CCR for implantable devices of 0.309 from the FY 2019 IPPS/LTCH PPS final rule (83 FR 41273) to the cost of the device. According to the applicant, no further charges or related charges were added. Based on the FY 2019 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case-weighted threshold amount was $172,965. The final average case-weighted standardized charge per case was $195,799. Because the final average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion. We are inviting public comments on whether DuraGraft® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the use of DuraGraft® significantly reduces clinical complications, such as MI, repeat revascularization and MACE, associated with VGF following CABG surgery. The applicant cited the following studies and report, each of which is summarized below, to substantiate its assertions regarding substantial clinical improvement: (1) Project of Ex-vivo Vein Graft Engineering via Transfection (PREVENT IV) Subanalysis; (2) European Retrospective Pilot Study (unpublished); (3) U.S. Department of Veterans Affairs (USDVA) Hospital Retrospective Study; and (4) the SWEDEHEART 2016 Annual Report.

PREVENT IV is a prospective study that enrolled 3,000 patients and included protocol driven angiograms at 12 months post-CABG, as opposed to clinically-driven angiograms to evaluate the true incidence of VGF following CABG surgery where standard-of-care solutions were used.[141] Harskamp, et al. conducted subanalyses of the study data and found from dozens of factors evaluated for impact on the development of 12-month VGF (VGF was defined as a stenosis of the vein graft diameter of 75 percent or greater) that exposure to solutions used in PREVENT IV (saline, blood, or buffered saline) for intra-operative graft wetting and storage have the largest correlation with the development of VGF.[142] [143]

[141] Alexander, J.H., Hafley, G., Harrington, R.A., et al., ''Efficacy and safety of Edifoligide, an E2F Transcription Factor Decoy, for Prevention of Vein Graft Failure Following Coronary Artery Bypass Graft Surgery: PREVENT IV: A Randomized Controlled Trial,'' *JAMA,* 2005, vol. 294, pp. 2446–54.

[142] Harskamp, R.E., Alexander, J.H., Schulte, P.J., Brophy, C.M., Mack, M.J., Peterson, E.D., Williams, J.B., Gibson, C.M., Califf, R.M., Kouchoukos, N.T., Harrington, R.A., Ferguson, Jr., T.B., Lopes, R.D., ''Vein Graft Preservation Solutions, Patency, and Outcomes After Coronary Artery Bypass Graft Surgery Follow-up From PREVENT IV Randomized Clinical Trial,'' *JAMA Surg.,* 2014, vol. 149(8), pp. 798–805.

[143] Hess, C.N., Lopes, R.D., Gibson, C.M., et al., ''Saphenous vein graft failure after coronary artery

According to the applicant, short-term exposure of free vascular grafts to these solutions is routine in CABG operations, where 10 minutes to 3 hours may elapse between the vein harvest and reperfusion.[144] [145] According to Harskamp, et al., the results of the PREVENT IV study showed that the majority of patients had grafts preserved in saline, 1,339 patients (44.4 percent), followed by 971 patients (32.2 percent) with grafts preserved in blood, and 507 patients (16.8 percent) with grafts preserved in buffered saline. One-year VGF rates were much lower in the patients who were treated in the buffered saline group than in the patients who were treated in the saline group (patient-level odds ratio [OR], 0.59 [95 percent CI, 0.45–0.78; *P*<.001]; graft-level OR, 0.63 [95 percent CI, 0.49–0.79; *P*<.001]) or in the patients who were treated in the blood group (patient-level OR, 0.62 [95 percent CI, 0.46–0.83; *P*=.001]; graft-level OR, 0.63 [95 percent CI, 0.48–0.81; *P*<.001]), and the use of buffered saline solution also tended to be associated with a lower 5-year risk for death, MI or subsequent revascularization compared with saline (hazard ratio, 0.81 [95 percent CI, 0.46–0.83; *P*=.001]; graft-level OR, 0.63 [95 percent CI, 0.48–0.81; *P*<.001]).[146] The applicant asserted that the results from the PREVENT IV subanalyses support the notion that unlike DuraGraft®, standard-of-care solutions heparinized saline and heparinized autologous blood used for intra-operative graft wetting and storage, were never designed to protect vascular grafts and have also demonstrated an inability to protect against ischemic injury, actively harming the graft endothelium as well.[147] [148] [149] [150]

In order to assess clinical outcomes associated with the use of DuraGraft®, the applicant opted to use readily available databases associated with two hospitals that had noncommercial access to the product through hospital pharmacies and, therefore, had real world use of DuraGraft® treatment. The two retrospective cohort studies, the European Retrospective Pilot Study and the USDVA Hospital Retrospective Study, used these data bases to evaluate the effectiveness and safety of the use of DuraGraft® during CABG surgical procedures for post-CABG clinical complications associated with VGF, including MI, repeat revascularization and MACE.

The European Retrospective Pilot Study (which was a feasibility study) was a retrospective study conducted to assess the safety and efficacy of DuraGraft® treatment on both short (less than 30 days) and long-term (greater than or equal to 30 days and up to 5 years) clinical outcomes. This study became the basis for the design of a larger retrospective study conducted at the USDVA Hospital, discussed below. The feasibility study is unpublished.

The European Retrospective Pilot study is a single-center clinical study of CABG patients to evaluate the potential benefits of DuraGraft® treatment as compared to a no-treatment control group (saline). The investigator, who prepared the analysis, remained blinded to individual patient data. A total of 630 patients who underwent elective and isolated CABG surgery with at least one saphenous vein graft between January 2002 and December 2008 were included. Eligibility criteria were: (1) Patients with first-time CABG surgery in which at least one vein graft was used; and (2) patients with in-situ internal mammary artery (IMA) graft(s) only (no saphenous vein or free arterial grafts). The single patient exclusion criteria were concomitant valve surgery and/or aortic aneurysm repair. The institutional review board of the University Health Alliance (UHA) approved the protocol, and patients gave written informed consent for their follow-up. The no-treatment control group (saline) included 375 patients who underwent CABG surgery from January 2002 to May 2005, and the DuraGraft® treatment group included 255 patients who underwent CABG surgery from June 2005 to December 2008. During long-term follow-up, 5 patients were lost to follow-up, and 10 patients died before the 30-day follow-up. Therefore, a total of 247 patients from the DuraGraft® treatment group (97 percent) and 368 patients from the no-treatment control group (saline) (98 percent) were available for the long-term analysis. Patients undergoing CABG surgery whose vascular grafts were treated intra-operatively with DuraGraft® demonstrated no statistically significant differences in MACE within the first 30 days following CABG surgery. According to the applicant, these data suggest that DuraGraft® treatment is at least as safe as the standard-of-care used in CABG surgeries. Long-term outcomes between the two groups were not statistically different. However, also according to the applicant, a consistent numerical trend toward improved clinical outcomes for the DuraGraft® treatment group compared to the no-treatment control (saline) group was clearly identified. Although statistically insignificant, there was a consistent reduction observed in the rates for multiple endpoints such as all-cause death, MI, MACE, and revascularization. This study found reductions in DuraGraft®-treated grafts relative to saline for revascularization (57 percent), MI (70 percent), MACE (37 percent), and all-cause death (23 percent) compared to standard-of-care (heparinized saline/blood) through 5 years follow-up. According to the applicant, based on the small sample size for this evaluation of less than 630 patients and the known frequencies of these events following CABG surgeries, statistical differences were not expected. A subsequent post-hoc analysis also was performed by the researchers at CHU Angers to evaluate whether any long-term clinical variables (such as dual antiplatelet therapy, beta-blockers, angiotensin receptor-blockers, statins, diabetes, lifestyle and other factors) had any impact on the clinical outcomes of the study. The conclusions of the post-hoc analyses were that the assessed long-term clinical variables did not impact the clinical study outcomes.

The second study, the USDVA Hospital Retrospective Study, was an unpublished, independent PI initiated, single-center, multi-surgeon, retrospective, comparative (DuraGraft® vs. Saline) clinical trial, which was conducted to assess the safety and impact of DuraGraft® treatment on both short and long-term clinical outcomes in patients who underwent isolated CABG surgery with saphenous vein grafts (SVGs) at the Boston (West Roxbury) VA

bypass surgery: insights from PREVENT IV,'' Circulation, 2014 Oct 21, vol. 130(17), pp. 1445–51.

[144] Motwani, J.G., Topol, E.J., ''Aortocoronary saphenous vein graft disease: pathogenesis, predisposition and prevention,'' Circulation, 1998, vol. 97(9), pp. 916–31.

[145] Mills, N.L., Everson, C.T., ''Vein graft failure,'' *Curr Opin Cardiol,* 1995, vol. 10, pp. 562–8.

[146] Harskamp, R.E., Alexander, J.H., Schulte, P.J., Brophy, C.M., Mack, M.J., Peterson, E.D., Williams, J.B., Gibson, C.M., Califf, R.M., Kouchoukos, N.T., Harrington, R.A., Ferguson, Jr., T.B., Lopes, R.D., ''Vein Graft Preservation Solutions, Patency, and Outcomes After Coronary Artery Bypass Graft Surgery Follow-up From PREVENT IV Randomized Clinical Trial,'' *JAMA Surg.,* 2014, vol. 149(8), pp. 798–805.

[147] Ibid.

[148] Weiss, D.R., et al., ''Extensive deendothelialization and thrombogenicity in routinely prepared vein grafts for coronary bypass operations: facts and remedy,'' *Int J Clin Exp Med,* 2009; vol. 2, pp. 95–113.

[149] Wilbring, M., Tugtekin, S.M., Zatschler, B., Ebner, A., Reichenspurner, H., Matschke, K., Deussen, A., ''Even short-time storage in physiological saline solution impairs endothelial vascular function of saphenous vein grafts,'' *Eur J Cardiothorac Surg.,* 2011 Oct, vol. 40(4), pp. 811–815.

[150] Thatte, H.S., Biswas, K.S., Najjar, S.F., Birjiniuk, V., Crittenden, M.D., Michel, T., and Khuri, S.F., ''Multi-Photon Microscopic valuation of Saphenous Vein Endothelium and Its Preservation With a New Solution, GALA.'' *Annals Thoracic Surgery,* 2003, vol. 75, pp. 1145–52.

Medical Center between 1996 and 2004. From 1996 through 1999, DuraGraft® treatment was not available and heparinized saline was routinely used to wet and store grafts. From 2001 through 2004, the Boston VA Medical Center began exclusively using DuraGraft®, which was prepared by the hospital's pharmacy. The applicant highlighted that 2000 data was omitted from this analysis by the PI due to the transition into the use of DuraGraft® and the uncertainty of whether DuraGraft® or heparinized saline was used in CABG patients during the transition period. Short-term clinical outcomes were defined as perioperative and early post-operative events occurring within the first 30 days after CABG including perioperative MI, prolonged ventilation time (greater than 48 hours), prolonged time in a coma (greater than 24 hours), renal failure, and death. Long-term clinical outcomes were defined as events occurring greater than 30 days after CABG including the need for repeat revascularization (that is, repeat CABG or percutaneous coronary intervention [PCI]), non-fatal acute MI (NFMI), all-cause death, and a composite of these MACE. The primary study outcome was repeat revascularization, and the secondary outcomes included MACE, NFMI, and all cause death.

According to the applicant, although the study represents the non-contemporaneous use of saline and DuraGraft®, the potential effect of ''time of CABG'' on outcomes was minimized in large part by the fact that this was a single-center study in which the same surgeons performed surgeries throughout the timeframe of this study. Additionally, the applicant explained that published evidence (including evidence collected from the same center) indicates that outcomes from CABG surgery such as mortality, MI, and repeat revascularization have not changed significantly between the time of this study and the present day, suggesting that surgical and medical improvements, differences in patient selection, and other factors which may have occurred over the timeframe of the study likely had little influence over the study results and, therefore, the statistically significant differences that were observed are due to ''study article'' effect.[151] [152] [153]

Data were extracted from a total of 2,436 patients who underwent a CABG procedure with at least 1 SVG from 1996 through 1999 (saline control n=1,400 patients) and 2001 through 2004 (DuraGraft® treatment n=1,036 patients). Patients were excluded from the study if they had a prior history of CABG, had no use of SVG, or underwent additional procedures during the CABG surgery.

Review of patient characteristics between the two treatment arms found the median age for the control group was 66 years old and 67 years old for the DuraGraft® treatment group. Mean follow-up in the control treatment group was 9.9±5.6 years and 8.5±4.2 years for the DuraGraft® treatment group.

Short-term clinical outcomes showed frequencies for individual outcomes were low, at less than 5 percent for both treatment groups. However, according to the applicant, there was a statistically significant 77 percent reduction of perioperative MI in the DuraGraft® group compared to the saline group, which may have indicated a potential short-term benefit related to preserving the endothelium.

Long-term clinical outcomes for patients treated with DuraGraft® compared to saline showed DuraGraft® patients with significantly lower risk of repeat revascularization (primary endpoint), non-fatal MI, and MACE outcomes. According to the applicant, the frequency of repeat revascularization was significantly lower after DuraGraft® treatment starting at 1,000 days onwards with a statistically significant adjusted 35 percent risk reduction. Additionally, the applicant noted that the use of DuraGraft® was associated with significantly lower risk for non-fatal MI beginning at 30 days post CABG with an adjusted risk reduction of 36 percent (HR:0.687; 95 percent CI: 0.499, 0.815; p=0.0003). This effect was even more profound at 1,000 days onward, with a statistically significant risk reduction of up to 45 percent. Finally, the applicant noted that the occurrence of MACE was significantly reduced after DuraGraft® treatment, with an adjusted risk reduction of 19 percent starting at 1,000 days after CABG. Both crude and inverse probability weighting (IPW) adjusted models for these long-term outcomes were summarized. Long-term mortality was comparable between treatment groups: neither the crude nor IPW-adjusted model showed a significant association between DuraGraft® exposure and time to death, either beginning 30 days or 1,000 days after initial CABG surgery. According to the applicant, this study supports not only safety, but also improved long-term clinical outcomes in DuraGraft®-treated CABG patients.

According to the applicant, the data collected from this statistically-powered USDVA Hospital Retrospective Study are consistent with data collected in the European Retrospective Pilot Study in which trend toward reductions of MI, repeat revascularization, and MACE were observed in the DuraGraft® treatment group, lending confidence that the observed trends in this study, as well as the European Retrospective Pilot Study, represent real differences associated with DuraGraft® use.

The applicant also referenced data from the SWEDEHEART 2016 Annual Report, a report on data extracted from the Swedish Cardiac Surgery Registry, to assess whether changes in the surgical procedure and post-op medications over the timeline of the USDVA Hospital Retrospective Study could have impacted the clinical outcomes. The applicant believed that these mortality data, which overlapped with the timeframe of the USDVA Hospital Retrospective Study, would provide an indication of whether such changes in the CABG procedure occurred over the relevant time period.

The applicant stated that the SWEDEHEART 2016 Annual Report was published in 2017 and documented a fairly constant mortality rate between 1995 and 2005 (we refer readers to the table below), which overlapped the timeframe of the USDVA Hospital Retrospective Study (1996 through 2004). The applicant noted that the data from the SWEDEHEART 2016 Annual Report was extracted from the Swedish Cardiac Surgery Registry, which collects data from all centers that are performing, or have been performing, cardiac surgery in Sweden since 1992 and maintains 100 percent of the data covering the number of adult cardiac surgery procedures. The applicant indicated that mortality data are derived from the Swedish national population registry and, therefore, are considered 100 percent complete and accurate. The applicant noted that the 30-day mortality rate between 1996 and 2004 (the timeframe of the USDVA Hospital Retrospective Study) remained fairly constant, even with CABG procedures performed by several different hospitals and surgeons. According to the applicant, these data indicate that

[151] Goldman, S., Zadina, K., Mortiz, T., et al., ''Long-term patency of saphenous vein and left internal mammary grafts after coronary artery bypass surgery: results from a Department of Veterans Affairs Cooperative Study,'' *J Am Coll Cardiol,* 2004, vol. 44, pp. 2149–2156.

[152] Granger, D.N. and Kvietys, P.R., ''Reperfusion Injury and Reactive Oxygen Species: The Evolution of a Concept.'' Redox Biol. 2015 Dec; 6: 524–551. Published online 2015 Oct 8. doi: 10.1016/j.redox.2015.08.020.

[153] Guibert, E.E., Petrenko, A.Y., Balaban, C.L., Somov, A.Y., Rodriguez, J.V., and Fuller, B.J., ''Organ Preservation: Current Concepts and New Strategies for the Next Decade,'' *Transfus Med Hemother,* 2011, vol. 38, pp. 125–142.

changes in the CABG procedure itself over the USDVA Hospital Retrospective Study time period were not significant enough to impact post-op mortality.

30-DAY MORTALITY RATE (%) BETWEEN 1995 AND 2005 BASED ON SWEDEHEART 2016 ANNUAL REPORT

Year	Isolated CABD volume	30-day mortality rate (%)
1995	6,001	1.9
1996	6,283	2.2
1997	5,076	1.7
1998	5,797	2
1999	5,504	1.9
2000	5,478	2.2
2001	5,696	1.8
2002	5,645	1.9
2003	5,245	1.9
2004	4,868	2
2005	4,264	1.7

According to the applicant, the European Retrospective Pilot Study and the USDVA Hospital Study demonstrated an association of reduced risk of non-fatal MI, repeat revascularization, and MACE with DuraGraft® treatment. However, we have a number of concerns relating to whether these results support a finding of substantial clinical improvement. We note that these studies are unpublished and consist of a retrospective design, which may contribute to potential sources of error such as confounding and bias. Moreover, the studies do not account for other variables that may affect vein integrity such as method of vein harvest, vein distention pressure, and controlling for the use of glycoprotein (GP) IIb/IIIa inhibitors.[154] [155]

With regard to the European Retrospective Pilot study, specifically, we are concerned that there are no defined primary and secondary long-term outcomes, no statistical plans to incorporate adjustments for multiple comparisons, and no power calculations for the expected differences in endpoints that would be biologically important. Furthermore, we are concerned that saline was used as the control, as opposed to buffered saline, which at the time was considered to be more effective than saline and, therefore, may have been a more optimal comparator.[156] We also are concerned that certain information was not available, including mean follow-up, patient-years follow-up and loss-to-follow-up. Finally, the study did not appear to convey any statistical differences for any of the short-term or long-term endpoints.

With regard to the USDVA Hospital Retrospective Study, we note that this study used heparinized saline as the comparator rather than buffered saline. According to a survey published in 2015 of 90 major U.S. medical centers, 40 percent were using buffered saline.[157] Also, we are concerned that the study population was limited to USDVA hospital patients and was overwhelmingly white (95 percent) males (99 percent), due to the demographics available through the USDVA hospital data source. We are concerned that this may affect the completeness of the study and raise questions as to whether the data and results are generalizable to other patient groups, to include, as acknowledged by the applicant, nonveterans, women, and other racial/ethnic groups. We also note that patients in the heparinized saline arm appeared to have more comorbidities, more vein grafts, fewer arterial grafts and more time on cardiopulmonary bypass as compared to the DuraGraft® treatment arm suggesting there may have been differences in the health of the patients in the two treatment arms prior to participation in the study. Without more context explaining the cause of each of these characteristics it may be difficult to substantiate the validity of the study results. We also believe that it would have been helpful to include coronary imaging studies with the results of the USDVA Hospital Retrospective Study to correlate MI and revascularizations with vein grafts. Without data from such studies, it is more difficult to associate the solutions with the repeat revascularization outcomes.

Furthermore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20308) we noted our concern regarding the timeframe differences in the saline and DuraGraft® arms in the USDVA Hospital Retrospective Study. As discussed earlier in this section, the applicant expressed that, although the USDVA Hospital Retrospective Study represents the non-contemporaneous use of saline and DuraGraft®, the potential effect of ''time of CABG'' on outcomes was minimized in large part by the fact that this was a single-center study in which the same surgeons performed surgeries throughout the timeframe of this study. The applicant also expressed that outcomes from CABG surgery such as mortality, MI, and repeat revascularization have not changed significantly between the time of the USDVA Hospital Retrospective Study and the present day, suggesting that surgical and medical improvements that may have occurred over the timeframe of the study likely had little influence over the study results and, therefore, the statistically significant differences that were observed are due to ''study article'' effect.[158] [159] [160] We appreciate the

[154] King, S., Short, M., Harmon, C., ''Glycoprotein IIb/IIIa inhibitors: the resurgence of tirofiban,'' *Vascul Pharmacol,* 2016 March; vol. 78, pp. 10–16.

[155] Harskamp, R.E., Hoedemaker, N., Newby, L.K., Woudstra, P., Grundeken, M.J., Beijk, M.A., Piek, J.J., Tijssen, J.G., Mehta, R.H., de Winter, R.J., ''Procedural and clinical outcomes after use of the glycoprotein IIb/IIIa inhibitor abciximab for saphenous vein graft interventions,'' *Cardiovasc Revasc Med,* 2016 Jan–Feb, vol. 17(1), pp. 19–23. Epub 2015 Oct 31. PMID: 26626961.

[156] Williams, J.B., Harskamp, R.E., Bose, S., Lawson, J.H., Alexander, J.H., Smith, P.K., Lopes, R.D., ''The Preservation and Handling of Vein Grafts in Current Surgical Practice: Findings of a Survey Among Cardiovascular Surgeons of Top-Ranked US Hospitals,'' *JAMA Surg,* 2015 Jul, vol. 150(7), pp. 681–3. PMID: 25970819.

[157] Ibid.

[158] Goldman, S., Zadina, K., Mortiz, T., et al., ''Long-term patency of saphenous vein and left internal mammary grafts after coronary artery bypass surgery: results from a Department of Veterans Affairs Cooperative Study,'' *J Am Coll Cardiol,* 2004, vol. 44, pp. 2149–2156.

[159] Granger, D.N. and Kvietys, P.R., ''Reperfusion Injury and Reactive Oxygen Species: The Evolution of a Concept,'' *Redox Biol,* 2015 Dec, vol. 6, pp. 524–551. Published online 2015 Oct 8. doi: 10.1016/j.redox.2015.08.020.

[160] Guibert, E.E., Petrenko, A.Y., Balaban, C.L., Somov, A.Y., Rodriguez, J.V., and Fuller, B.J., ''Organ Preservation: Current Concepts and New Strategies for the Next Decade,'' *Transfus Med Hemother,* 2011, vol. 38, pp. 125–142.

applicant identifying and speaking to this concern, as it was raised by CMS in the FY 2019 IPPS/LTCH PPS proposed rule. However, we remain concerned that the timeframe differences between the saline and DuraGraft® arms in the USDVA Hospital Retrospective Study were not accounted for in the analysis of the retrospective data taken from the study.

Additionally, although the applicant provided an explanation about how to match patients via propensity scores, we are concerned that the statistical plan did not include adjustments for multiple comparisons nor did it include power calculations for the expected differences in endpoints that would be biologically important.

The applicant also provided information from the USDVA Hospital Retrospective Study that suggested there are a significant number of MACE-type events in the first 3 years after CABG. However, much of the long-term data for the control group was missing, in particular, data related to the first 30 to 999 days post-CABG. Finally, regarding the secondary long-term-outcome of MACE, we are concerned the study did not appear to include coronary cardiac mortality, non-coronary cardiac mortality, and other cardiac morbidity within the definition of MACE.

Also, as discussed above, the applicant referenced data from the SWEDEHEART 2016 Annual Report, which noted a decline in the number of CABG procedures (by approximately ⅓) between 1996 and 2005. It is unclear what contributed to the decline in CABG procedures during this time period, particularly because, as the applicant indicated, mortality rates remained fairly constant throughout this timeframe. We believe the decline in the number of CABG procedures may also reflect time-related differences in surgical management.

We are inviting public comments on whether DuraGraft® meets the substantial clinical improvement criterion. We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for DuraGraft® or at the New Technology Town Hall meeting.

f. Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific Corporation submitted an application for new technology add-on payments for the Eluvia™ Drug-Eluting Vascular Stent System for FY 2020. Eluvia™, a drug-eluting stent for the treatment of lesions in the femoropopliteal arteries, received FDA premarket approval (PMA) on September 18, 2018.

According to the applicant, the Eluvia™ system is a sustained-release drug-eluting stent indicated for improving luminal diameter in the treatment of peripheral artery disease (PAD) with symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and or proximal popliteal artery (PPA) with reference vessel diameters (RVD) ranging from 4.0 to 6.0 mm and total lesion lengths up to 190 mm.

The applicant stated that PAD is a circulatory condition in which narrowed arteries reduce blood flow to the limbs, usually in the legs. Symptoms of PAD may include lower extremity pain due to varying degrees of ischemia, claudication which is characterized by pain induced by exercise and relieved with rest. According to the applicant, risk factors for PAD include individuals who are age 70 years old and older; individuals who are between the ages of 50 years old and 69 years old with a history of smoking or diabetes; individuals who are between the ages of 40 years old and 49 years old with diabetes and at least one other risk factor for atherosclerosis; leg symptoms suggestive of claudication with exertion, or ischemic pain at rest; abnormal lower extremity pulse examination; known atherosclerosis at other sites (for example, coronary, carotid, renal artery disease); smoking; hypertension, hyperlipidemia, and homocysteinemia.[161] PAD is primarily caused by atherosclerosis—the buildup of fatty plaque in the arteries. PAD can occur in any blood vessel, but it is more common in the legs than the arms. Approximately 8.5 million people in the United States have PAD, including 12 to 20 percent of individuals who are age 60 years old and older.[162]

A diagnosis of PAD is established with the measurement of an ankle-brachial index (ABI) less than or equal to 0.9. The ABI is a comparison of the resting systolic blood pressure at the ankle to the higher systolic brachial pressure. Duplex ultrasonography is commonly used, in conjunction with the ABI, to identify the location and severity of arterial obstruction.[163]

Management of the disease is aimed at improving symptoms, improving functional capacity, and preventing amputations and death. Management of patients who have been diagnosed with lower extremity PAD may include medical therapies to reduce the risk for future cardiovascular events related to atherosclerosis, such as myocardial infarction, stroke, and peripheral arterial thrombosis. Such therapies may include antiplatelet therapy, smoking cessation, lipid-lowering therapy, and treatment of diabetes and hypertension. For patients with significant or disabling symptoms unresponsive to lifestyle adjustment and pharmacologic therapy, intervention (percutaneous, surgical) may be needed. Surgical intervention includes angioplasty, a procedure in which a balloon-tip catheter is inserted into the artery and inflated to dilate the narrowed artery lumen. The balloon is then deflated and removed with the catheter. For patients with limb-threatening ischemia (for example, pain while at rest and or ulceration), revascularization is a priority to reestablish arterial blood flow. According to the applicant, treatment of the SFA is problematic due to multiple issues including high rate of restenosis and significant forces of compression.

The applicant describes Eluvia™ Drug-Eluting Vascular Stent System as a sustained-release drug-eluting self-expanding, nickel titanium alloy (nitinol) mesh stent used to reestablish blood flow to stenotic arteries. According to the applicant, the Eluvia™ stent is coated with the drug paclitaxel, which helps prevent the artery from restenosis. The applicant stated that Eluvia™'s polymer-based drug delivery system is uniquely designed to sustain the release of paclitaxel beyond 1 year to match the restenotic process in the SFA. According to the applicant, the Eluvia™ Stent System is comprised of: (1) The implantable endoprosthesis; and (2) the stent delivery system (SDS). On both the proximal and distal ends of the stent, radiopaque markers made of tantalum increase visibility of the stent to aid in placement. The tri-axial designed delivery system consists of an outer shaft to stabilize the stent delivery system, a middle shaft to protect and constrain the stent, and an inner shaft to provide a guide wire lumen. The delivery system is compatible with

[161] Neschis, David G. & MD, Golden, M., ''Clinical features and diagnosis of lower extremity peripheral artery disease.'' Available at: *https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-lower-extremity-peripheral-artery-disease.*

[162] Centers for Disease Control and Prevention, ''Peripheral Arterial Disease (PAD) Fact Sheet,'' 2018, Retrieved from *https://www.cdc.gov/DHDSP/data_statistics/fact_sheets/fs_PAD.htm.*

[163] Berger, J. & Davies, M., ''Overview of lower extremity peripheral artery disease,'' Retrieved October 29, 2018, from *https://www.uptodate.com/contents/overview-of-lower-extremity-peripheral-artery-disease.*

0.035 in (0.89 mm) guide wires. The Eluvia™ stent is available in a variety of diameters and lengths. The delivery system is offered in 2 working lengths (75 cm and 130 cm).

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would, therefore, not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, according to the applicant, Eluvia™ uses a unique mechanism of action which has not been utilized by previously available medical devices for treating stenotic lesions in the SFA. The applicant asserted that the Eluvia™ Drug-Eluting Vascular Stent System is a device/drug combination product composed of an implantable stent, combined with a polybutyl methacrylate (PBMA) primer layer, a paclitaxel/polyvinylidene difluoride (PVDF) polymer, and a stent delivery system. According to the applicant, the polymer carries and protects the drug before and during the procedure and ensures that the drug is released into the tissue in a controlled, sustained manner to prevent restenosis of the vessel. According to the applicant, the Eluvia™ system continues to deliver paclitaxel to combat restenosis for 12 to 15 months, which involves a novel and distinct mechanism of action different than other drug-coated balloons or drug-coated stents that only deliver the drug to the artery for about 2 months. According to the applicant, the PBMA polymer is clinically proven to permit the sustained release of paclitaxel to achieve a therapeutic outcome. We note that, the applicant submitted a request for consideration for approval at the March 2019 ICD–10 Coordination and Maintenance Committee Meeting for a unique ICD–10–PCS procedure code to describe procedures which use the Eluvia™ stent system.

With regard to the second criterion, whether a technology is assigned to the same or a different MS–DRG, the applicant asserted that patients who may be eligible for treatment using the Eluvia™ system include hospitalized patients who have been diagnosed with PAD. According to the applicant, these potential cases may map to multiple MS–DRGs, the most likely being MS–DRGs 252 (Other Vascular Procedures With MCC), 253 (Other Vascular Procedures With CC) and 254 (Other Vascular Procedures Without CC/MCC). Potential cases representing patients who may be eligible for treatment using the Eluvia™ system would be assigned to the same MS–DRGs as cases representing hospitalized patients who have been diagnosed with PAD and treated with currently available technologies.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, according to the applicant, clinical conditions that may require use of the Eluvia™ stent system include treatment of the same patient population as cases identified with a variety of diagnosis codes from the ICD–10–CM category I70 (Atherosclerosis) as listed in the table below:

ICD–10–CM diagnosis code	Code description
I70.201	Unspecified atherosclerosis of native arteries of extremities, right leg.
I70.202	Unspecified atherosclerosis of native arteries of extremities, left leg.
I70.203	Unspecified atherosclerosis of native arteries of extremities, bilateral legs.
I70.208	Unspecified atherosclerosis of native arteries of extremities, other extremity.
I70.209	Unspecified atherosclerosis of native arteries of extremities, unspecified extremity.
I70.211	Atherosclerosis of native arteries of extremities with intermittent claudication, right leg.
I70.212	Atherosclerosis of native arteries of extremities with intermittent claudication, left leg.
I70.213	Atherosclerosis of native arteries of extremities with intermittent claudication, bilateral legs.
I70.218	Atherosclerosis of native arteries of extremities with intermittent claudication, other extremity.
I70.219	Atherosclerosis of native arteries of extremities with intermittent claudication, unspecified extremity.
I70.221	Atherosclerosis of native arteries of extremities with rest pain, right leg.
I70.222	Atherosclerosis of native arteries of extremities with rest pain, left leg.
I70.223	Atherosclerosis of native arteries of extremities with rest pain, bilateral legs.
I70.228	Atherosclerosis of native arteries of extremities with rest pain, other extremity.
I70.229	Atherosclerosis of native arteries of extremities with rest pain, unspecified extremity.
I70.231	Atherosclerosis of native arteries of right leg with ulceration of thigh.
I70.232	Atherosclerosis of native arteries of right leg with ulceration of calf.
I70.233	Atherosclerosis of native arteries of right leg with ulceration of ankle.
I70.234	Atherosclerosis of native arteries of right leg with ulceration of heel and midfoot.
I70.235	Atherosclerosis of native arteries of right leg with ulceration of other part of foot.
I70.238	Atherosclerosis of native arteries of right leg with ulceration of other part of lower right leg.
I70.239	Atherosclerosis of native arteries of right leg with ulceration of unspecified site.
I70.241	Atherosclerosis of native arteries of left leg with ulceration of thigh.
I70.242	Atherosclerosis of native arteries of left leg with ulceration of calf.
I70.243	Atherosclerosis of native arteries of left leg with ulceration of ankle.
I70.244	Atherosclerosis of native arteries of left leg with ulceration of heel and midfoot.
I70.245	Atherosclerosis of native arteries of left leg with ulceration of other part of foot.
I70.248	Atherosclerosis of native arteries of left leg with ulceration of other part of lower left leg.
I70.249	Atherosclerosis of native arteries of left leg with ulceration of unspecified site.
I70.25	Atherosclerosis of native arteries of other extremities with ulceration.
I70.261	Atherosclerosis of native arteries of extremities with gangrene, right leg.
I70.262	Atherosclerosis of native arteries of extremities with gangrene, left leg.
I70.263	Atherosclerosis of native arteries of extremities with gangrene, bilateral legs.
I70.268	Atherosclerosis of native arteries of extremities with gangrene, other extremity.
I70.269	Atherosclerosis of native arteries of extremities with gangrene, unspecified extremity.
I70.291	Other atherosclerosis of native arteries of extremities, right leg.
I70.292	Other atherosclerosis of native arteries of extremities, left leg.
I70.293	Other atherosclerosis of native arteries of extremities, bilateral legs.

ICD–10–CM diagnosis code	Code description
I70.298	Other atherosclerosis of native arteries of extremities, other extremity.
I70.299	Other atherosclerosis of native arteries of extremities.

The applicant asserted that the Eluvia™ stent is not substantially similar to any existing technology because it uses a unique mechanism of action, when compared to existing technologies, to achieve a therapeutic outcome and, therefore, meets the newness criterion.

We are concerned as to whether the polymer drug carrier system that the Eluvia™ system uses is, in fact, a new mechanism of action as compared to stents that contain paclitaxel without the carrier polymer. We are concerned that the Eluvia™ device may have a mechanism of action similar to the paclitaxel-coated Zilver® Drug-Eluting Peripheral Stent, which is indicated for improving luminal diameter for the treatment of de novo or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameter from 4 mm to 7 mm and total lesion lengths up to 300 mm per patient. We are inviting public comments on whether the Eluvia™ system is substantially similar to existing technology and whether it meets the newness criterion, including with respect to the concerns we have raised. With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion.

As noted earlier, the applicant asserted that cases involving the treatment of PAD, involving treatment of lesions in the femoropopliteal arteries typically, map to MS–DRGs 252, 253, and 254. The applicant searched the FY 2017 MedPAR data file in MS–DRGs 252, 253 and 254 for cases reporting an ICD–10–PCS procedure code for the treatment of Peripheral BMS or DES, which the applicant believed would represent cases potentially eligible for the use of the Eluvia™ stent system. The applicant identified 109,747 claims for cases representing patients who may be eligible for treatment involving the Eluvia™ stent system. The applicant applied the following trims: Claims paid under GHO (that is, Medicare beneficiaries enrolled in a Medicare Advantage managed care plan), claims for CAHs, IPFs, IRFs, LTCHs, Children's, Cancer, and RHNCI hospitals excluding Maryland acute-care hospitals, claims with total charges or lengths-of-stay of less than or equal to zero, claims with total charge differing from sum of charges of the 19 cost groups by greater than $30, providers that do not have charges greater than $0 for at least 14 of the 19 cost groups, claims with total charges for the MS–DRG +/− 3 standard deviations from the log mean total charges or charges per day, ''IME only'' claims submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage plan, claims with claim types ''61 to 64'' (that is, claim types that refer to encounter claims, Medicare Advantage IME, and HMO no-pay claims), and claims for which the applicant was unable to calculate standardized charges (because the Provider Number associated with the claim does not appear in the FY 2017 impact file). This resulted in 73,861 claims across MS–DRGs 252, 253, and 254.

Using the 73,861 claims, the applicant determined an average case-weighted unstandardized charge per case of $96,232. The applicant removed all device-related charges and then standardized the charges for each case and inflated each case's charges by applying the FY 2019 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.08864 (83 FR 41722). (We note that the 2-year charge inflation factor was revised in the FY 2019 IPPS/LTCH PPS final rule correction notice to 1.08986 (83 FR 49844). We further note that even when using the corrected final rule values to inflate the charges, the average case-weighted standardized charge per case for each scenario exceeded the average case-weighted threshold amount.) The applicant then added charges for Eluvia™ by taking the cost of the device and converting it to a charge by dividing the costs by the national average CCR of 0.309 for devices from the FY 2019 IPPS/LTCH PPS final rule (83 FR 41273). The applicant calculated an average case-weighted standardized charge per case of $86,950 using the percent distribution of MS–DRGs as case-weights. Based on this analysis, the applicant determined that the final inflated average case-weighted standardized charge per case for Eluvia™ exceeded the average case-weighted threshold of $81,518 by $5,432.

The applicant conducted additional analyses to demonstrate it meets the cost criterion. In these analyses, the applicant repeated the cost analysis above with one analysis of cases reporting the ICD–10–PCS procedures codes for Peripheral DES procedures and the other analysis with cases reporting the ICD–10–PCS procedures codes for Peripheral BMS procedures. In each of these additional sensitivity analyses, the final inflated average case-weighted standardized charge per case exceeded the average case-weighted cost threshold amount. We are inviting public comments on whether Eluvia™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the Eluvia™ Drug-Eluting Vascular Stent System represents a substantial clinical improvement over existing technologies because it achieves superior primary patency; reduces the rate of subsequent therapeutic interventions; decreases the number of future hospitalizations or physician visits; reduces hospital readmission rates; reduces the rate of device-related complications; and achieves similar functional outcomes and EQ–5D index values while associated with half the rate of target lesion revascularizations (TLRs).

The applicant submitted the results of the MAJESTIC study, a single-arm, first-in-human study of Eluvia™. The MAJESTIC [164] study is a prospective, multi-center, single-arm, open-label study. According to the applicant, the MAJESTIC study demonstrated long-term treatment durability among patients whose femoropopliteal arteries were treated with the Eluvia™ stent. The applicant asserts that the MAJESTIC study demonstrates the sustained impact of the Eluvia™ stent on primary patency. The MAJESTIC study enrolled 57 patients who had been diagnosed with symptomatic lower limb ischemia and lesions in the superficial femoral artery or proximal popliteal artery. Efficacy measures at 2 years included primary patency, defined as duplex ultrasound peak systolic velocity ratio of less than 2.5 and the absence of target lesion revascularization (TLR) or bypass. Safety monitoring through 3 years included adverse events and TLR. The

[164] Müller-Hülsbeck, S., et al., ''Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Follow-up,'' *Cardiovasc Intervent Radiol,* December 2017, vol. 40(12), pp. 1832–1838.

24-month clinic visit was completed by 53 patients; 52 had Doppler ultrasound evaluable by the core laboratory, and 48 patients had radiographs taken for stent fracture analysis. The 3-year follow-up was completed by 54 patients. At 2 years, 90.6 percent (48/53) of the patients had improved by 1 or more Rutherford categories as compared with the pre-procedure level without the need for TLR (when those with TLR were included, 96.2 percent sustained improvement); only 1 patient exhibited a worsening in level, 66.0 percent (35/53) of the patients exhibited no symptoms (category 0) and 24.5 percent (13/53) had mild claudication (category 1) at the 24-month visit. Mean ABI improved from 0.73 ± 0.22 at baseline to 1.02 ± 0.20 at 12 months and 0.93 ± 0.26 at 24 months. At 24 months, 79.2 percent (38/48) of the patients had an ABI increase of at least 0.1 compared with baseline or had reached an ABI of at least 0.9. The applicant also noted that at 12 months the Kaplan–Meier estimate of primary patency was 96.4 percent.

With regard to the Eluvia™ stent achieving superior primary patency, the applicant submitted the results of the IMPERIAL [165] study in which the Eluvia™ stent is compared, head-to-head, to the Zilver® PTX Drug-Eluting stent. The IMPERIAL study is a global, multi-center, randomized controlled trial consisting of 465 subjects. Eligible patients were aged 18 years old or older and had a diagnosis of symptomatic lower-limb ischaemia, defined as Rutherford Category 2, 3, or 4 and stenotic, restenotic (treated with a drug-coated balloon greater than 12 months before the study or standard percutaneous transluminal angioplasty only), or occlusive lesions in the native superficial femoral artery or proximal popliteal artery, with at least 1 infrapopliteal vessel patent to the ankle or foot. Patients had to have stenosis of 70 percent or more (via angiographic assessment), vessel diameter between 4 mm and 6 mm, and total lesion length between 30 mm and 140 mm.

Patients who had previously stented target lesion/vessels treated with drug-coated balloon less than 12 months prior to randomization/enrollment and patients who had undergone prior surgery of the SFA/PPA in the target limb to treat atherosclerotic disease were excluded from the study. Two concurrent single-group (Eluvia™ only) sub-studies were done: A non-blinded, non-randomized pharmacokinetic sub-study and a non-blinded, non-randomized study of patients who had been diagnosed with long lesions (greater than 140 mm in diameter). The IMPERIAL study is a prospective, multi-center, single-blinded randomized, controlled (RCT) non-inferiority trial. Patients were randomized (2:1) to implantation of either a paclitaxel-eluting polymer stent (Eluvia™) or a paclitaxel-coated stent (Zilver® PTX) after the treating physician had successfully crossed the target lesion with a guide wire. The primary endpoints of the study are Major Adverse Events defined as all causes of death through 1 month, Target Limb Major Amputation through 12 months and/or Target Lesion Revascularization (TLR) through 12 months and primary vessel patency at 12 months post-procedure. Secondary endpoints included the Rutherford categorization, Walking Impairment Questionnaire, and EQ–5D assessments at 1 month and 6 months post-procedure. Patient demographic and characteristics were balanced between Eluvia™ stent and Zilver® PTX stent groups.

The applicant noted that lesion characteristics for the patients in the Eluvia™ stent versus the Zilver® PTX stent arms were comparable. Clinical follow-up visits related to the study were scheduled for 1 month, 6 months, and 12 months after the procedure, with follow-up planned to continue through 5 years, including clinical visits at 24 months and 5 years and clinical or telephone follow-up at 3 and 4 years.

The applicant asserted that in the IMPERIAL study the Eluvia™ stent demonstrated superior primary patency over the Zilver® PTX stent, 86.8 percent versus 77.5 percent, respectively (p=0.0144). The non-inferiority primary efficacy endpoint was also met. The applicant asserts that the SFA presents unique challenges with respect to maintaining long-term patency. There are distinct pathological differences between the SFA and coronary arteries. The SFA tends to have higher levels of calcification and chronic total occlusions when compared to coronary arteries. Following an intervention within the SFA, the SFA produces a healing response which often results in restenosis or re-narrowing of the arterial lumen. This cascade of events leading to restenosis starts with inflammation, followed by smooth muscle cell proliferation and matrix formation.[166] Because of the unique mechanical forces in the SFA, this restenotic process of the SFA can continue well beyond 300 days from the initial intervention. Results from the IMPERIAL study showed that primary patency at 12 months, by Kaplan-Meier estimate, was significantly greater for Eluvia™ than for Zilver® PTX, 88.5 percent and 79.5 percent, respectively (p=0.0119). According to the applicant, these results are consistent with the 96.4 percent primary patency rate at 12 months in the MAJESTIC study.

The IMPERIAL study included two concurrent single-group (Eluvia™ only) sub-studies: A non-blinded, non-randomized pharmacokinetic sub-study and a non-blinded, non-randomized study of patients with long lesions (greater than 140 mm in diameter). For the pharmacokinetic sub-study, patients had venous blood drawn before stent implantation and at intervals ranging from 10 minutes to 24 hours post implantation, and again at either 48 hours or 72 hours post implantation. The pharmacokinetics sub-study confirmed that plasma paclitaxel concentrations after Eluvia™ stent implantation were well below thresholds associated with toxic effects in studies in patients who had been diagnosed with cancer (0.05 μM or ~43 ng/mL).

The IMPERIAL sub-study long lesion subgroup consisted of 50 patients with average lesion length of 162.8 mm that were each treated with two Eluvia™ stents. According to the applicant, 12-month outcomes for the long lesion subgroup are 87 percent primary patency and 6.5 percent Target Lesion Revascularization (TLR). According to the applicant, in a separate subgroup analysis of patients 65 years old and older (Medicare population), the primary patency rate in the Eluvia™ stent group is 92.6 percent, compared to 75.0 percent for the Zilver® PTX stent group (p=0.0386).

With regard to reducing the rate of subsequent therapeutic interventions, secondary outcomes in the IMPERIAL study included repeat re-intervention on the same lesion, target lesion revascularization (TLR). The rate of subsequent interventions, or TLRs, in the Eluvia™ stent group was 4.5 percent compared to 9.0 percent in the Zilver® PTX stent group. The applicant asserted that the TLR rate in the Eluvia™ group represents a substantial reduction in re-intervention on the target lesion compared to that of the Zilver® PTX stent group.

[165] Gray, W.A., et al., ''A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial,'' *Lancet,* September 24, 2018.

[166] Forrester, J.S., Fishbein, M., Helfant, R., Fagin, J., ''A paradigm for restenosis based on cell biology: clues for the development of new preventive therapies,'' *J Am Coll Cardiol,* March 1, 1991, vol. 17(3), pp. 758–69.

With regard to decreasing the number of future hospitalizations or physician visits, the applicant asserted that the substantial reduction in the lesion revascularization rate led to a reduced need to provide additional intensive care, distinguishing the Eluvia™ group from the Zilver® PTX stent group. In the IMPERIAL study, Eluvia™-treated patients required fewer days of re-hospitalization. Patients in the Eluvia™ group averaged 13.9 days of re-hospitalization for all adverse events compared to 17.7 days of re-hospitalization for patients in the Zilver® PTX stent group. Patients in the Eluvia™ group were re-hospitalized for 2.8 days for TLR/Total Vessel Revascularization (TVR) compared to 7.1 days in the Zilver® PTX stent group. And lastly, patients in the Eluvia™ group were re-hospitalized for 2.7 days for procedure/device-related adverse events compared to 4.5 days from the Zilver® PTX stent group.

With regard to reducing hospital readmission rates, the applicant asserted that patients treated in the Eluvia™ group experienced reduced rates of hospital readmission following the index procedure compared to those in the Zilver® PTX stent group. Hospital readmission rates at 12 months were 3.9 percent for the Eluvia™ group compared to 7.1 percent for the Zilver® PTX stent group. Similar results were noted at 1 and 6 months; 1.0 percent versus 2.6 percent and 2.4 percent versus 3.8 percent, respectively.

With regard to reducing the rate of device-related complications, the applicant asserted that while the rates of adverse events were similar in total between treatment arms in the IMPERIAL study, there were measurable differences in device-related complications. Device-related adverse-events were reported in 8 percent of the patients in the Eluvia™ group compared to 14 percent of the patients in the Zilver® PTX stent group.

Lastly, with regard to achieving similar functional outcomes and EQ–5D index values, while associated with half the rate of TLRs, the applicant asserted that narrowed or blocked arteries within the SFA can limit the supply of oxygen-rich blood throughout the lower extremities, causing pain or discomfort when walking (claudication). The applicant further asserted that performing physical activities is often challenging because of decreased blood supply to the legs, typically causing symptoms to become more challenging over time unless treated. While functional outcomes appear similar between the Eluvia™ and Zilver® PTX stent groups at 12 months, these improvements for the Zilver® PTX stent group are associated with twice as many TLRs to achieve similar EQ–5D index values.[167] Secondary endpoints improved after stent implantation and were generally similar between the groups. At 12 months, of the patients with complete Rutherford assessment data, 241 (86 percent) of 281 patients in the Eluvia™ group and 120 (85 percent) of 142 patients in the Zilver® PTX group had symptoms reported as Rutherford Category 0 or 1 (none to mild claudication). The mean ankle-brachial index was 1.0 (SD 0.2) in both groups at 12 months (baseline mean ankle-brachial index 0.7 [SD 0.2] for Eluvia™; 0.8 [0.2] for Zilver® PTX), with sustained hemodynamic improvement for approximately 80 percent of the patients in both groups. Walking function improved significantly from baseline to 12 months in both groups, as measured with the Walking Impairment Questionnaire and the 6-minute walk test. In both groups, the majority of patients had sustained improvement in the mobility dimension of the EQ–5D and roughly half had sustained improvement in the pain or discomfort dimension. No significant between-group differences were observed in the Walking Impairment Questionnaire, 6-minute walk test, or EQ–5D. Secondary endpoint results for the Eluvia™ stent and Zilver® PTX stent groups are as follows:

- Hemodynamic improvement in walking—80.8 percent versus 78.7 percent;
- Walking impairment questionnaire scores (change from baseline)—40.8 (36.5) versus 35.8 (39.5);
- Distance (change from baseline)—33.2 (38.3) versus 29.5 (38.2);
- Speed (change from baseline)—18.3 (29.5) versus 18.1 (28.7);
- Stair climbing (change from baseline)—19.4 (36.7) versus 21.1 (34.6); and
- 6-Minute walk test distance (m) (change from baseline)—44.5 (119.5) versus 51.8 (130.5).

We are concerned that the IMPERIAL study, which showed significant differences in primary patency at 12 months, was designed for non-inferiority and not superiority. We also note the results of a recently published meta-analysis of randomized controlled trials of the risk of death associated with the use of paclitaxel-coated balloons and stents in the femoropopliteal artery of the leg, which found that there is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs and that further investigations are urgently warranted,[168] although the Eluvia™ system was not included in the meta-analysis. We are inviting public comments on whether the Eluvia™ system meets the substantial clinical improvement criterion, including the implications of the conclusion of the meta-analysis results with respect to a finding of substantial clinical improvement for Eluvia™.

Below we summarize and respond to a written public comment we received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Eluvia™.

Comment: With regard to the applicant's assertion that the Eluvia™ stent achieves statistically superior primary patency over the Zilver® PTX stent, the commenter noted that the non-inferior primary patency of Eluvia™ as compared to the Zilver® PTX stent was the primary efficacy endpoint of the IMPERIAL study. The commenter stated that the authors of the IMPERIAL study published a paper in The Lancet that noted a post-hoc analysis that suggested that Eluvia™'s primary patency was superior to Zilver® PTX stent. The commenter further noted that in the FY 2020 New Technology Add-On Payment Town Hall presentation, the Eluvia™ Drug-Eluting Vascular Stent System's presenter used this analysis as a predicator to substantiate the substantial clinical improvement provided by the use of the Eluvia™ stent. The commenter questioned the basis of the applicant's assertion of substantial clinical improvement contingent upon this rationale because, according to the commenter, primary patency in this study was measured by duplex ultrasound obtained on each enrollee at 12 months. The commenter indicated that this is an endpoint based on imaging, and in and of itself, may not have any direct clinical significance. The commenter suggested that a loss of patency alone, without an associated recurrence or increase of clinical signs or symptoms (pain, walking impairment, ulcer development, etc.,) is

[167] Gray, W.A., Keirse, K., Soga, Y., et al., ''A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomized, non-inferiority trial,'' Lancet, 2018, published online Sept 22, *http://dx.doi.org/10.1016/S0140-6736(18)32262-1.*

[168] Katsanos, K., et al., ''Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials,'' *JAHA,* vol. 7(24).

not a clinically-relevant measure. As such, the commenter believed that the rationale used in that post-hoc analysis to determine superiority in primary patency does not offer support for an assertion of clinical improvement. The commenter noted that it is an interesting finding, but as discussed further below, the commenter does not believe this translates into a representation of substantial clinical improvement. The commenter further stated that ''the pre-specified primary endpoint of the study indicated non-inferiority of primary patency of Eluvia™ when compared to the Zilver® PTX stent, with a non-significant difference of 5.3 percent (95 percent confidence interval: −2.5 percent, 13.1 percent); and this information was not included in the New Technology Town Hall presentation''.

With regard to the applicant's assertion that the Eluvia™ stent reduces the rate of subsequent therapeutic interventions by 50 percent, the commenter noted that ''Subsequent Therapeutic Interventions'' was not further defined in the New Technology Town Hall presentation nor in the IMPERIAL study. The commenter stated that it would appear from the presentation materials, however, that it is referring specifically to ''target lesion revascularizations (TLR)''.

The commenter referred to the Eluvia™ New Technology Town Hall presentation slide deck, and stated that the presenter displayed graphs showing ''Clinically-driven TLR Rates'' for both the Eluvia™ stent and the Zilver® PTX stent. The commenter stated that the graph showed a TLR rate for Eluvia™ of 4.5 percent, and a corresponding TLR rate of 9.0 percent for the Zilver® PTX stent, with that slide also displaying a p-value of 0.0672. The commenter explained that because a p-value of less than 0.05 is widely accepted in the scientific and clinical communities as a threshold to establish a statistically significant difference, a p-value of 0.0672 suggests that the difference between the devices' TLR rates is not statistically significant. The commenter believed that, given that the difference in TLR rates is not statistically significant, no conclusions can or should be drawn regarding substantial clinical improvement based on these TLR rates. The commenter stated that the Lancet study paper itself reported a TLR rate of 4.5 percent for Eluvia™ and 8.7 percent for the Zilver® PTX stent, with an even higher p-value of 0.0746,[169] and the commenter believes that the difference in TLR rates is more questionably meaningful. With regard to the applicant's assertion that Eluvia™ achieves similar functional outcomes with half as many TLRs (repeat procedures) at 1 year, the commenter stated that based on the data presented during the New Technology Town Hall presentation and discussed at length in the Lancet study paper, ''functional'' clinical outcomes between the Eluvia™ and the Zilver® PTX patients were similar. These clinical outcome measures included walking function (assessed with the Walking Impairment Questionnaire and 6-minute walk test), Rutherford scores, EQ–5D quality of life scores, and ankle-brachial index measures. The commenter believed that these similar results dispute the conclusion that Eluvia™ represents a substantial clinical improvement compared to the Zilver® PTX stent. Further, the commenter stated that this section of the presentation once again references and is based on the difference in TLR rates. As noted above, the commenter believed that this difference in rates was not demonstrated to be significant and, therefore, should not be the basis for a conclusion of clinical improvement. Additionally, the commenter also noted that, although not described in the New Technology Town Hall presentation, the Lancet publication indicates that the calculations of clinical improvement and hemodynamic improvement already account for TLR as a failure. Therefore, the commenter believed that stating that the outcomes are similar with half as many TLRs is misleading. The commenter further stated that similar clinical outcomes and TLR rates do support the study's conclusions of non-inferiority, but should not form the basis for an assertion of superiority.

With regard to the applicant's assertion that the use of the Eluvia™ stent reduces hospital readmission rates, the commenter noted that during the New Technology Town Hall presentation, the presenter noted that the Eluvia™ group had a hospital readmission rate at 12 months of 3.9 percent compared to the Zilver® PTX group's rate of 7.1 percent, and that no p-value was included on the slide used for the presentation to offer an assessment of the statistical significance of this difference. The commenter noted that this particular data comparison was not discussed in the main body of the Lancet paper, but could be found in the online appendix. The commenter further noted that as with the presentation slide, no p-value was offered in the appendix. The commenter indicated that its statistics team did, however, calculate a p-value of 0.17 for this comparison. The commenter noted that a p-value of 0.17 is well above the standard p-value threshold of 0.05 needed to draw a conclusion of statistical significance. Given that this difference is not statistically significant, the commenter believed that based on this submitted data, this assertion should also not be used to substantiate a representation of substantial clinical improvement for the Eluvia™ stent.

With regards to longer-term data on the Zilver® PTX stent and the Eluvia™ stent, the commenter noted that in the commentary in The Lancet paper accompanying the IMPERIAL study, Drs. Salvatore Cassese and Robert Byrne write that a follow-up duration of 12 months is insufficient to assess late failure, which is not infrequently observed. According to Drs. Cassese and Byrne, the preclinical models of restenosis after stenting of peripheral arteries have shown that stents permanently overstretch the arterial wall, thus stimulating persistent neointimal growth, which might cause a catch-up phenomenon and late failure. The paper noted that in this regard, data on outcomes beyond 1 year will be important to confirm the durability of the efficacy of the Eluvia™ stent.[170] The commenter stated that at this point in time, very limited longer-term data is available on the use of the Eluvia™ stent and that the IMPERIAL study offers only 12-month data, although data out to 3 years has been published from the relatively small 57-patient single-arm MAJESTIC study. The commenter noted that the MAJESTIC study demonstrates a decrease in primary patency from 96.4 percent at 1 year to 83.5 percent at 2 years; and a doubling in TLR rates from 1 year to 2 years (3.6 percent to 7.2 percent) and again from 2 years to 3 years (7.2 percent to 14.7 percent). The commenter stated that this is not inconsistent with Drs. Cassese and Byrne's commentary regarding late failure, and that the relatively small, single-arm design of the study does not lend itself well to direct comparison to other SFA treatment options such as the Zilver® PTX stent.

The commenter stated that Eluvia™'s lack of long-term data contrasts with 5-year data that is available from the Zilver® PTX stent's pivotal 479-patient

[169] Gray, W.A., et al., ''A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial,'' *Lancet,* September 24, 2018.

[170] Cassese, S., & Byrne, R.E., ''Endovascular stenting in femoropopliteal arteries,'' *The Lancet,* 2018, vol. 392(10157), pp. 1491–1493.

RCT comparing the use of the Zilver® PTX stent to angioplasty (with a sub-randomization comparing provisional use of Zilver® PTX stenting to bare metal Zilver stenting in patients experiencing an acute failure of percutaneous transluminal angioplasty (PTA)). The commenter believed that these 5-year data demonstrate that the superiority of the use of the Zilver® PTX stent demonstrated at 12 and 24 months is maintained through 5 years compared to PTA and provisional bare metal stenting, and actually increases rather than decreases over time. The commenter also believed that, given that these stent devices are permanent implants and they are used to treat a chronic disease, long-term data is important to fully understand an SFA stent's clinical benefits. The commenter stated that with 5-year data available to support the ongoing safety and effectiveness of the use of the Zilver® PTX stent, but no such corresponding data available for the use of the Eluvia™ stent, it seems incongruous to suggest that the use of the Eluvia™ stent results in a substantial clinical improvement compared to the Zilver® PTX stent.

The commenter further stated that, in addition to the very limited long-term data available for the Eluvia™ stent, there is also a lack of clinical data for the use of the Eluvia™ stent to confirm the benefit of the device outside of a strictly controlled clinical study population. The commenter stated that in contrast, the Zilver® PTX stent has demonstrated comparable outcomes across a broad patient population, including a 787-patient study conducted in Europe with 2-year follow-up and a 904-patient study of all-comers (no exclusion criteria) in Japan with 5-year follow-up completed. The commenter believed that with no corresponding data for the use of the Eluvia™ stent in a broad patient population, it seems unreasonable to suggest that the use of the Eluvia™ stent results in a substantial clinical improvement compared to the Zilver® PTX stent.

Response: We appreciate the information provided by the commenter. We will take these comments into consideration when deciding whether to approve new technology add-on payments for the Eluvia™ Drug-Eluting Vascular Stent System for FY 2020.

g. ELZONRIS™ (tagraxofusp, SL–401)

Stemline Therapeutics submitted an application for new technology add-on payments for ELZONRIS™ for FY 2020. ELZONRIS™ (tagraxofusp, SL–401) is a targeted therapy for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) administered via infusion. The applicant stated that BPDCN, previously known as blastic natural killer (NK) cell leukemia/lymphoma, is a rare, highly aggressive hematologic malignancy with a median overall survival of 8 to 14 months from diagnosis that occurs predominantly in the elderly (median age at diagnosis is 67 years old) and in male patients (75 percent). The applicant cited data from the Surveillance, Epidemiology, and End Results Program (SEER) registry that the estimated incidence of BPDCN is less than 100 new cases per year in the U.S. However, the applicant believes that registries likely underestimate the true incidence of BPDCN due to changing nomenclature and lack of a standardized disease characterization prior to 2008, and that additional patients may be eligible for treatment.

According to the applicant, ELZONRIS™ is a targeted therapy directed to the interleukin-3 receptor (IL–3 receptor). The IL–3 receptor is composed of two chains: An alpha chain, also known as CD123, and a β chain. Together, the two chains form a high-affinity cell surface receptor for interleukin-3 (IL–3). The binding of IL–3 to the IL–3 receptor initiates signaling that stimulates the proliferation and differentiation of certain hematopoietic cells. The alpha unit of the IL–3 receptor (also known as CD123) has also been found to be expressed in a variety of cancers, including BPDCN, a malignancy derived from plasmacytoid dendrite cells (pDCs).

The applicant explained that ELZONRIS™ is a recombinant protein composed of human IL–3 genetically fused to a truncated diphtheria toxin (DT) payload. The applicant stated that ELZONRIS™ binds with high affinity to the IL–3 receptor and is engineered such that IL–3 replaces the native receptor-binding domain of DT and thereby acts like a homing device, targeting the DT cytotoxic payload specifically to CD123-expressing cells. Upon binding to the IL–3 receptor, ELZONRIS™ is internalized into endosomes, where the low pH environment enables proteolytic cleavage and release of the catalytic domain of DT into the cytoplasm. The target of DT's catalytic domain is elongation factor 2 (EF–2), a key protein involved in protein translation. Inactivation of EF–2 leads to termination of protein synthesis, which ultimately results in cell death. The applicant asserted that ELZONRIS™ is engineered such that IL–3 targets the cytotoxic payload specifically to CD123-expressing cells.

The applicant indicated that the regimens historically employed for the treatment of patients who have been diagnosed with BPDCN have generally consisted of those regimens, or modified versions of those regimens, used for aggressive hematologic malignancies, including regimens normally used in the treatment of acute lymphoblastic leukemia, acute myeloid leukemia, and lymphoma. The applicant summarized the mechanisms of various drugs and regimens currently used to treat BPDCN, including:

- *Etoposide,* which the applicant explained works by inhibiting topoisomerase II, which in turn disrupts the ligation step of the cell cycle, leading to apoptosis and cell death.
- *Hyper CVAD,* which the applicant explained is a regimen consisting of cyclophosphamide, vincristine and doxorubicin, dexamethasone, methotrexate, and cytarabine. Cyclophosphamide damages DNA by binding to it and causing the formation of cross-links. Vincristine prevents cell duplication by binding to the protein tubulin. Dexamethasone is a steroid to counteract side effects. Methotrexate is an antimetabolite that competitively inhibits an enzyme that is used in in folate synthesis, arresting cell reproduction.
- *CHOP,* which the applicant explained is a regimen of cyclophosphamide, doxorubicin, vincristine, and prednisone.
- *AspaMetDex L-asparaginase, Methotrexate, Dexamethasone.* The applicant explained that L-asparaginase catalyzes the conversion of L-asparagine to aspartic acid and ammonia, depriving leukemic cells of L-asparagine, leading to cell death.
- *Ara-C regimen (cytarabine),* which the applicant explained interferes with synthesis of DNA by altering the sugar component of nucleosides.

The applicant stated that there are no approved therapies or established standards of care for the treatment of patients who have been diagnosed with BPDCN, either for treatment-naive or previously-treated patients. The applicant asserted that current treatments for patients who have been diagnosed with BPDCN might temporarily help to slow disease progression, but they fail to eradicate cancer stem cells (CSCs), and no specific treatment regimen has been shown to be effective or is recommended. According to the applicant, only half of reported patients show initial response to the regimens historically employed for treatment of a diagnosis of BPDCN, and these reported responses do not generally appear to be

durable, with many patients experiencing a quick relapse. Overall survival is typically low, ranging from 8 to 14 months across various treatment regimens.

With respect to the newness criterion, according to the applicant, the FDA accepted the applicant's Biologics License Application (BLA) filing for ELZONRIS™ in August 2018 for the treatment of patients who have been diagnosed with blastic plasmacytoid dendritic cell neoplasm. The FDA granted this application Breakthrough Therapy, Priority Review, and Orphan Drug designations, and on December 21, 2018, approved ELZONRIS™ for the treatment of blastic plasmacytoid dendritic cell neoplasm in adults and in pediatric patients 2 years old and older. Currently, there are no ICD–10–PCS procedure codes to uniquely identify procedures involving ELZONRIS™. We note that the applicant has submitted a request for approval for a unique ICD–10–PCS code for the administration of ELZONRIS™ beginning in FY 2020.

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, according to the applicant, ELZONRIS™ treats BPDCN via target antigen specificity, attacking cells with the IL–3 receptor (CD123) overexpressed in cancer stem cells (CSCs) and tumor bulk, but minimally expressed or absent on normal hematopoietic stem cells. The applicant indicated that ELZONRIS™'s mechanism of action involves a receptor-mediated endocytosis, inhibition of protein synthesis, and interference with IL–3 signal transduction pathways, leading to growth arrest and apoptosis in leukemia blasts and CSCs. The applicant asserted that current BPDCN treatments are not targeted, and their mechanisms of action aim to arrest quickly-dividing cells through DNA alkylation and intercalation, as well as through protein binding to prevent cell duplication. The applicant also asserted that current treatments for patients who have been diagnosed with BPDCN might temporarily help to slow disease progression, but they fail to eradicate CSCs. The applicant stated that in contrast, ELZONRIS™ utilizes a payload that is not cell cycle-dependent and, therefore, it is able to kill not just highly proliferative tumor bulk, but also the relatively quiescent CSCs. The applicant noted that there are similar targeted therapies currently under investigation, although the applicant asserted that these other therapies are all in much earlier stages of development. Therefore, the applicant asserted that ELZONRIS™ utilizes a different mechanism of action than currently available treatment options.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that because BPDCN is a distinct and rare hematologic malignancy and there are no other approved therapies or established standard-of-care, cases representing patients receiving treatment involving ELZONRIS™ would not be assigned to the same MS–DRG(s) when compared to cases representing patients receiving treatment involving existing technologies. We note that, as explained below in the discussion of the cost criterion, the applicant stated that potential cases representing patients who may be eligible for treatment involving ELZONRIS™ would be assigned to MS–DRGs that contain cases representing patients who are receiving chemotherapy without acute leukemia as a secondary diagnosis.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, the use of ELZONRIS™ would involve treatment of a dissimilar patient population as compared to other therapies. The applicant stated that the World Health Organization standardized the current name and specific category of disease for BPDCN in 2016, designating it as a distinct entity within the acute myeloid neoplasms and acute leukemias. The applicant indicated that no BPDCN standard-of-care has been established and currently patients who have been diagnosed with BPDCN are being treated with therapies used for other diseases. Therefore, the applicant asserted that ELZONRIS™ would be used in the treatment of a new patient population because the patient population in question is distinguishable from others by the ICD–10–CM diagnosis code specific to BPDCN: C86.4 (Blastic NK-cell lymphoma), for which there is no specific treatment regimen that has been shown to be effective or is recommended, as stated above.

As summarized above, the applicant maintains that ELZONRIS™ meets the newness criterion and is not substantially similar to existing technologies because it has a unique mechanism of action; potential cases representing patients who may be eligible for treatment involving the use of ELZONRIS™ would be assigned to a different MS–DRG when compared to existing technologies; and the use of the technology would treat a new patient population. We are inviting public comments on whether ELZONRIS™ is substantially similar to any existing technologies and whether ELZONRIS™ meets the newness criterion.

With regard to the cost criterion, the applicant used the FY 2017 MedPAR Hospital Limited Data Set (LDS) to assess the MS–DRGs to which cases representing potential patient hospitalizations that may be eligible for treatment involving ELZONRIS™ would most likely be assigned. The applicant identified these potential cases using the ICD–10–CM diagnosis code C86.4 (Blastic NK-cell lymphoma), which the applicant stated is another name for BPDCN. The applicant identified 65 cases reporting ICD–10–CM diagnosis code C86.4 spanning 28 different MS–DRGs. The applicant asserted that cases representing patients hospitalized who may be eligible to receive treatment involving ELZONRIS™ would most likely appear in MS–DRGs 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC) and 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC). Therefore, the applicant limited the analysis to the cases in MS–DRG 847 and MS–DRG 846 that also reported the ICD–10–CM diagnosis code C86.4. The cases identified in these two MS–DRGs accounted for 24 (37 percent) of the 65 cases reporting ICD–10–CM diagnosis code C86.4.

The applicant indicated that because the number of cases reporting ICD–10–CM diagnosis code C86.4 is so low and it was difficult to discern the costs of the predecessor therapies that would be replaced by the use of ELZONRIS™, the applicant performed the cost criterion analysis under two different scenarios. Both scenarios use the 24 cases identified in the FY 2017 MedPAR data and increase the sample size by using an additional 18 cases identified in the FY 2016 MedPAR data mapping to the same MS–DRGs and reporting the same ICD–10–CM diagnosis code, for a combined total of 42 cases with an average case-weighted unstandardized charge per case of $67,947. For the first scenario, because the applicant was unable to determine the appropriate costs for the predecessor therapies, the applicant did not remove any predecessor charges from the cases analyzed, although the applicant noted that it might be extreme

to assume that no products or services would be replaced if ELZONRIS™ were used. For the second scenario, the applicant removed all charges from the cases so that only ELZONRIS™ was used as the cost of the case. The applicant characterized this as a conservative assumption, as it assumes that the only charges related to these cases would be the cost of ELZONRIS™.

The applicant then standardized the FY 2017 charges using the FY 2017 impact file and then inflated the charges to FY 2019 using the 2-year inflation factor of 8.59 percent (1.085868) that the applicant indicated was published in the FY 2019 IPPS/LTCH PPS final rule. The applicant standardized FY 2016 charges using the FY 2016 impact file and then inflated the charges to FY 2019 using a 3-year inflation factor of 13.15 percent (1.131529), which was calculated based on the 1-year inflation factor (1.04205) that the applicant indicated was listed in the FY 2019 IPPS/LTCH PPS final rule. We note that the inflation factors used by the applicant were the proposed 1-year and 2-year inflation factors, which were published in the FY 2019 IPPS/LTCH PPS final rule in the summary of FY 2019 IPPS proposals (83 FR 41718). The final 1-year and 2-year inflation factors published in the FY 2019 IPPS/LTCH PPS final rule are 1.04338 and 1.08864, respectively (83 FR 41722), and a 3-year inflation factor calculated based on these numbers is 1.13587. We note that these figures were revised in the FY 2019 IPPS/LTCH PPS final rule correction notice. The corrected final 1-year and 2-year inflation factors are 1.04396 and 1.08986, respectively (83 FR 49844), and a 3-year inflation factor calculated based on the corrected final numbers is 1.13776.

The applicant then added charges for ELZONRIS™ in both scenarios. To determine the charges for ELZONRIS™, the applicant calculated the average per discharge cost of ELZONRIS™ inflated by the inverse of the national average CCR for pharmacy costs of 0.191. The applicant then calculated an average case-weighted standardized charge per case for each scenario and compared it with the average case-weighted threshold amount. The applicant stated that ELZONRIS™ exceeded the average-case-weighted threshold amount under each scenario and, therefore, meets the cost criterion. Results of the analyses of both scenarios are summarized in the table below:

	Number of Medicare cases	Average case-weighted new technology add-on payment threshold	Final inflated average case-weighted standardized charge per case	Amount exceeded threshold
FY 2016 and FY 2017 MedPAR Data; No Predecessor Charges Removed	42	$52,049	$1,066,195	$1,014,146
FY 2016 and FY 2017 MedPAR Data; All Predecessor Charges Removed ..	42	52,049	1,010,455	958,406

We note that the applicant used the proposed rule values to inflate the standardized charges. However, we further note that even when using either the final rule values or corrected final rule values to inflate the charges, the average case-weighted standardized charge per case for each scenario exceeded the average case-weighted threshold amount. We are inviting public comments on whether ELZONRIS™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant stated that it believes ELZONRIS™ represents a substantial clinical improvement because: (1) ELZONRIS™ is the only treatment indicated specifically for the treatment of patients who have been diagnosed with BPDCN, a disease without a defined standard-of-care; (2) ELZONRIS™ offers a treatment option for a patient population ineligible for aggressive chemotherapy regimens used to treat BPDCN; (3) ELZONRIS™ exhibits high complete remission rates, potentially superior to other regimens used to treat a diagnosis of BPDCN; (4) ELZONRIS™ significantly improves overall survival (OS) in the treatment of patients diagnosed with BPDCN as compared to currently available treatment regimens; (5) ELZONRIS™ significantly improves clinical outcomes in the BPDCN patient population because it may allow more patients to bridge to stem cell transplantation, an effective treatment not currently administered to most patients due to their inability to tolerate the requisite conditioning therapies; (6) ELZONRIS™ exhibits a manageable profile that is consistent over increasing patient exposure and experience, demonstrating a well-tolerated targeted therapy suitable for the majority of patients who are unable to receive intensive chemotherapy; and (7) ELZONRIS™ is more efficient than other chemotherapeutic drugs at killing BPDCN in preclinical studies, suggesting clinical benefit would also be exhibited if head-to-head comparison was pursued.

In support of the claim that ELZONRIS™ is the only treatment indicated specifically for the treatment of patients who have been diagnosed with BPDCN, the applicant submitted a 2016 review article which indicated that no standardized therapeutic approach has been established yet for the treatment of BPDCN, and the optimal therapy remains to be defined.[171]

Second, in support of the claim that ELZONRIS™ offers a treatment option for a patient population ineligible for aggressive chemotherapy regimens used to treat BPDCN, the applicant submitted a 2016 review of treatment modalities for patients who have been diagnosed with BPDCN to establish that there is a clear unmet need for targeted treatment. The study reported that seven BPDCN patients treated with Hyper-CVAD, an aggressive chemotherapy regimen, achieved an overall response of 86 percent and complete remission of 67 percent; [172] however, the applicant noted that the evidence is limited to a small number of patients. Another 2016 review article indicated that supportive care or palliative chemotherapy is used in the treatment of many patients who have been diagnosed with BPDCN because of their age or comorbidities, and may be the only option for elderly patients with a low performance status or characterized by the presence of relevant co-morbidities, suggesting that targeted therapy has the potential for improving patient outcomes.[173]

[171] Pagano, L., Valentini, C.G., Grammatico, S., Pulsoni, A., ''Blastic plasmacytoid dendritic cell neoplasm: diagnostic criteria and therapeutical approaches,'' *British Journal of Haematology,* 2016, vol. 174(2), pp. 188–202.

[172] Falcone, U., Sibai, H., Deotare, U., ''A critical review of treatment modalities for blastic plasmacytoid dendritic cell neoplasm,'' *Critical Reviews in Oncology/Hematology,* 2016, vol. 107, pp. 156–162.

[173] Pagano, L., Valentini, C.G., Grammatico, S., Pulsoni, A., ''Blastic plasmacytoid dendritic cell

Third, the applicant maintained that ELZONRIS™ exhibits high complete remission rates, potentially superior to other regimens used to treat patients who have been diagnosed with BPDCN. The applicant submitted a 2013 retrospective case study of patients who had been diagnosed with BPDCN, in which 15/41 (37 percent) of evaluable patients achieved CR with induction therapies; 2 partial responders subsequently became complete responders with consolidation therapy (17/41: 41 percent). This study noted a high death rate of 17 percent following induction treatment.[174] The applicant reported prospective clinical trial data from ELZONRIS™'s pivotal trial (ELZONRIS™ 12 µg/kg/day), which observed a complete response plus a complete clinical response of 72 percent in treatment-naive patients (21/29 patients).[175]

Fourth, the applicant maintained that ELZONRIS™ significantly improves overall survival (OS) in patients who have been diagnosed with BPDCN as compared to currently available treatment regimens. The applicant submitted a 2013 retrospective case study of patients who have been diagnosed with BPDCN, which found that the median overall survival was just 8.7 months in 43 patients.[176] The applicant reported prospective clinical trial data from ELZONRIS™'s pivotal trial (ELZONRIS™ 12 µg/kg/day), which found that median overall survival has not yet been reached, with a median follow-up of 23 months [0.2 − 41 + months].[177]

Fifth, the applicant maintained that ELZONRIS™ significantly improves clinical outcomes in the treatment of the BPDCN patient population because it may allow more patients to bridge to stem cell transplantation, an effective treatment not currently administered to most patients due to their inability to tolerate the requisite conditioning therapies. The applicant submitted a 2011 retrospective study that included 6 cases of elderly patients who had been diagnosed with BPDCN in which 4 patients underwent allogenic stem cell transplantation (SCT) following moderately reduced intensity of conditioning chemotherapy regimens; 2 patients who received stem cell transplant while in remission lived disease free 57 months and 16 months post-SCT, and 2 patients transplanted with active disease achieved complete remission but relapsed 6 and 18 months after transplantation. Conditioning chemotherapy regimens were reduced in intensity due to the patients' elderly age.[178] The applicant also submitted a 2015 retrospective study of 25 BPDCN cases in which patients were treated with SCT. Of 11 BPDCN patients treated with autologous SCT and 14 patients treated with allogenic SCT, overall survival (OS) at 4 years was 82 percent and 69 percent, respectively, and no relapses were observed.[179] The applicant also submitted a 2013 retrospective study of 43 BPDCN cases in which only 6 out of 43 patients (14 percent) received allogenic SCT.[180] The applicant submitted a 2010 retrospective study of BPDCN cases in which only 10 out of 47 patients (21 percent) received SCT.[181] The applicant submitted a 2016 review article which concluded that early results from clinical trials for ELZONRIS™ indicate that it could be used to consolidate the effects of first-line chemotherapy and/or reduce minimal residual disease before allogenic SCT.[182] The applicant reported prospective clinical trial data from ELZONRIS™'s pivotal trial (ELZONRIS™ 12 µg/kg/day), for which the median age among the patients with BPDCN who received treatment involving ELZONRIS™ was 70 years old, in which 45 percent (13/29) of treatment-naïve patients treated with ELZONRIS™ (12 µg/kg/day) were bridged to SCT in remission.[183]

Sixth, the applicant maintained that ELZONRIS™ exhibits a manageable profile that demonstrates a well-tolerated targeted therapy suitable for the majority of patients who are unable to receive intensive chemotherapy. The prospective clinical trial data from ELZONRIS™'s pivotal trial (ELZONRIS™ 12 µg/kg/day) found that ELZONRIS™'s side effect profile remained consistent over increasing patient exposure and experience. No evidence of cumulative toxicity was seen over multiple cycles of ELZONRIS™.

Myelosuppression (thrombocytopenia, anemia, neutropenia) was modest, reversible, and was not dose-limiting for any patient. The most common treatment-related adverse events included increased alanine aminotransferase levels, increased aspartate aminotransferase levels and hypoalbuminemia, mostly restricted to the first cycle of therapy. The most serious side effect was capillary leak syndrome; most reports were Grade II in severity.[184]

Lastly, the applicant asserts that ELZONRIS™ is more efficient than other chemotherapeutic drugs at killing BPDCN in preclinical studies, suggesting clinical benefit would also be exhibited if head-to-head comparison to cytotoxic agents commonly used for the treatment of hematologic malignancies was pursued. The applicant submitted a 2015 preclinical study that found malignant cells from patients who had been diagnosed with BPDCN were more sensitive to ELZONRIS™ than to a wide variety of cytotoxic agents commonly used for treatment of hematologic malignancies, including drugs such as cytosine arabinoside, cyclophosphamide, vincristine, dexamethasone, methotrexate, Erwinia L-asparaginase, and asparaginase.[185]

neoplasm: diagnostic criteria and therapeutical approaches,'' *British Journal of Haematology,* 2016, vol. 174(2), pp. 188–202.

[174] Pagano, L., Valentini, C.G., Pulsoni, A., et al., for GIMEMA–ALWP (Gruppo Italiano Malattie EMatologiche dell'Adulto, Acute Leukemia Working Party), ''Blastic plasmacytoid dendritic cell neoplasm with leukemic presentation: an Italian multicenter study,'' *Haematologica,* 2013, vol. 98(2), pp. 239–246.

[175] Pemmaraju, N., et al., ''Results of Pivotal Phase 2 Trial of SL–401 in Patients with Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN),'' Proceedings from the 2018 European Hematology Association Congress, 2018, Abstract 214438.

[176] Pagano, L., Valentini, C.G., Pulsoni, A., *et al.,* for GIMEMA–ALWP (Gruppo Italiano Malattie EMatologiche dell'Adulto, Acute Leukemia Working Party), ''Blastic plasmacytoid dendritic cell neoplasm with leukemic presentation: an Italian multicenter study,'' *Haematologica,* 2013, vol. 98(2), pp. 239–246.

[177] Pemmaraju, N., *et al.,* ''Results of Pivotal Phase 2 Clinical Trial of Tagraxofusp (SL–401) in Patients with Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN),'' Proceedings from the 2018 American Society of Hematology (ASH), 2018, Abstract S765.

[178] Dietrich, S., *et al.,* ''Blastic plasmacytoid dendritic cell neoplasia (BPDC) in elderly patients: results of a treatment algorithm employing allogeneic stem cell transplantation with moderately reduced conditioning intensity,'' *Biology of Blood and Marrow Transplantation,* 2011, vol. 17, pp. 1250–1254.

[179] Aoki, T., *et al.,* ''Long-term survival following autologous and allogenic stem cell transplantation for Blastic plasmacytoid dendritic cell neoplasm,'' *Blood,* 2015, vol. 125(23), pp. 3559–3562.

[180] Pagano, L., Valentini, C.G., Pulsoni, A., *et al.,* for GIMEMA–ALWP (Gruppo Italiano Malattie EMatologiche dell'Adulto, Acute Leukemia Working Party), ''Blastic plasmacytoid dendritic cell neoplasm with leukemic presentation: an Italian multicenter study,'' *Haematologica,* 2013, vol. 98(2), pp. 239–246.

[181] Dalle, S., *et al.,* ''Blastic plasmacytoid dendritic cell neoplasm: is transplantation the treatment of choice?,'' *The British Journal of Dermatology,* 2010, vol. 162, pp. 74–79.

[182] Pagano, L., Valentini, C.G., Grammatico, S., Pulsoni, A., ''Blastic plasmacytoid dendritic cell neoplasm: diagnostic criteria and therapeutical approaches,'' *British Journal of Haematology,* 2016, vol. 174(2), pp. 188–202.

[183] Pemmaraju, N., *et al.,* ''Results of Pivotal Phase 2 Trial of SL–401 in Patients with Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN),'' Proceedings from the 2018 European Hematology Association Congress, 2018, Abstract 214438.

[184] Ibid.

[185] Angelot-Delettre, F., Roggy, A., Frankel, A.E., Lamarthee, B., Seilles, E., Biichle, S., *et al.,* ''In vivo and in vitro sensitivity of blastic plasmacytoid

Continued

After reviewing the information submitted by the applicant as part of its FY 2020 new technology add-on payment application for ELZONRIS™, we are concerned that some of the evidence submitted by the applicant to demonstrate substantial clinical improvement over existing technologies is based on preclinical studies. We also are unsure if the study populations in the 2013 retrospective study that the applicant used to compare remission rates are composed of treatment-naïve, previously-treated, or a mix of patients.

In addition, the applicant reported that the interim results of the Phase II trial of treatment of BPDCN with ELZONRIS ™ demonstrated high response rates in BPDCN, including: 90 percent overall response in treatment naïve patients (26/29) and 69 percent overall response in relapse/refractory patients (9/13); 72 percent complete response plus complete clinical response in treatment naïve patients (21/29) and 38 percent complete response plus complete clinical response in relapse/refractory patients (5/13); and 45 percent of patients treated in first-line setting were bridged to stem cell transplant in remission (13/29).[186] However, we are concerned that the small number of patients in the study and the lack of baseline data against which to compare this technology may make it more difficult to determine whether these interim results support a finding of substantial clinical improvement. We also note that because the clinical trial is ongoing and the final outcomes are not available, we are concerned that there may not be enough information on the efficacy to determine substantial clinical improvement at this time. We also note that the applicant's December 2018 New Technology Town Hall meeting presentation includes information that differs slightly from the application materials, and we are not clear whether the study results submitted with the application reflect the most current information available. We are inviting public comments on whether ELZONRIS ™ meets the substantial clinical improvement criterion, including with respect to the concerns we have raised.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ELZONRIS ™ or at the New Technology Town Hall meeting.

h. Erdafitinib

Johnson & Johnson Health Care Systems, Inc. (on behalf of Janssen Oncology, Inc.) submitted an application for new technology add-on payments for Erdafitinib for FY 2020. The proposed indication for the use of Erdafitinib is the second-line treatment of adult patients who have been diagnosed with locally advanced or metastatic urothelial carcinoma whose tumors exhibit certain fibroblast growth factor receptor (FGFR) genetic alterations as detected by an FDA-approved test, and who have disease progression during or following at least one line of prior chemotherapy including within 12 months of neoadjuvant or adjuvant chemotherapy.

According to the applicant, Erdafitinib is an oral pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor being evaluated in Phase II and III clinical trials in patients who have been diagnosed with advanced urothelial cancer. FGFRs are a family of receptor tyrosine kinases, which may be upregulated in various tumor cell types and may be involved in tumor cell differentiation and proliferation, tumor angiogenesis, and tumor cell survival. Erdafitinib is a pan-fibroblast FGFR inhibitor with potential antineoplastic activity. Upon oral administration, Erdafitinib binds to and inhibits FGFR, which may result in the inhibition of FGFR-related signal transduction pathways and, therefore, the inhibition of tumor cell proliferation and tumor cell death in FGFR-overexpressing tumor cells.

The applicant indicated that urothelial cancer (also known as transitional cell cancer or bladder cancer) is the sixth most common type of cancer diagnosed in the U.S. In 2018, an estimated 81,190 new cases of bladder cancer were expected to be diagnosed (approximately 62,380 in men and 18,810 in women), and result in 17,240 deaths (approximately 1 out of 5 diagnosed men and 1 out of 4 diagnosed women).[187] According to the applicant, for patients with metastatic disease, outcomes can be dire due to the often rapid progression of the tumor and the lack of efficacious treatments, especially in cases of relapsed or refractory disease. The applicant further stated that the relative 5-year survival rate for patients with metastatic disease is 5 percent.

According to the applicant, in regard to current second-line treatment, patients who have been diagnosed with locally advanced or metastatic urothelial cancer have limited options and favor anti-programmed death ligand 1/anti-programmed death 1 (anti-PD–L1/anti-PD–1) therapies (also known as checkpoint inhibitors) as opposed to conventional cytotoxic chemotherapy. With objective response rates ranging from approximately 20 to 25 percent with currently approved therapies and treatments, the applicant stated that new effective treatment options are needed for this patient population. Although there are five FDA-approved immune checkpoint inhibitors, the applicant stated that studies have shown that not all patients benefit from PD–1 blockade. The applicant explained that patients harboring FGFR alternates, which occurs at a frequency of approximately 20 percent, are thought to have immunologically ''cold tumors'' that are less likely to benefit from PD–1 blockade therapy.

The applicant noted that Erdafitinib was granted Breakthrough Therapy designation by the FDA on March 15, 2018, for the treatment of patients who have been diagnosed and treated for urothelial cancer whose tumors have certain FGFR genetic alterations. Erdafitinib has not received FDA premarket approval as of the time of the development of this proposed rule. Although there are no currently approved ICD–10–PCS procedure codes to uniquely identify the use of Erdafitnib, facilities can report the oral administration of Erdafitinib with the use of the following ICD–10–PCS code: 3E0DX05 (Introduction of Other Antineoplastic into Mouth and Pharynx, External Approach). We note that the applicant has submitted a request for approval at the March 2019 ICD–10 Coordination and Maintenance Committee Meeting for a unique ICD–10–PCS procedure code to specifically identify cases involving the administration of Erdafitinib. According to the applicant, this request was discussed at the September 11, 2018 ICD–10 Coordination and Maintenance Committee meeting, and at that meeting CMS recommended the establishment of a New Technology Section ''X'' code to distinctly identify cases involving the administration of Erdafitinib.

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be

dendritic cell neoplasm to SL–401, an interleukin-3 receptor targeted biologic agent,'' *Haematologica,* 2015, vol. 100(2), pp. 223–30.

[186] Pemmaraju, N., et al., ''Results of Pivotal Phase 2 Trial of SL–401 in Patients with Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN),'' Proceedings from the 2018 European Hematology Association Congress, 2018, Abstract 214438.

[187] American Cancer Society, ''Key Statistics for Bladder Cancer,'' *www.cancer.org/cancer/bladder-cancer/about/key-statistics.html.*

considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that Erdafitinib is not substantially similar to any existing treatment options because its inhibitory mechanism of action is novel. Specifically, the applicant stated that Erdafitinib is a pan-fibroblast FGFR inhibitor with potential antineoplastic activity. Upon oral administration, Erdafitinib binds to and inhibits FGFR, which may result in the inhibition of FGFR-related signal transduction pathways and, therefore, the inhibition of tumor cell proliferation and tumor cell death in FGFR-overexpressing tumor cells. The applicant stated that Erdafitinib is a potent pan-FGFR (1–4) tyrosine kinase inhibitor with IC50 (drug concentration at which 50 percent of target enzyme activity is inhibited) in the single-digit nanomolar range. According to the applicant, Erdafitinib will, therefore, represent a first-in-class FGFR inhibitor because of its novel mechanism of action.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that potential cases representing patients who may be eligible for treatment involving Erdafitinib are likely to be assigned to a wide variety of MS–DRGs because patients who may receive treatment involving Erdafitinib in the inpatient setting would likely be hospitalized due to other conditions than urothelial cancer. The applicant stated that potential cases representing patients who may be eligible for treatment involving the use of Erdafitinib may be assigned to the same MS–DRGs as cases representing patients treated with currently available treatment options for urothelial cancer.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted that the treatment involving Erdafitnib is specific to a select subset of patients who have been diagnosed with locally advanced or metastatic urothelial carcinoma and previously treated, but subsequently present with FGFR alterations. According to the applicant, while patients who have been diagnosed with metastatic or unresectable urothelial cancer may be offered second-line therapy options of a checkpoint inhibitor or systemic chemotherapy, treatment involving Erdafitinib is specific to a subset of patients with certain FGFR-genetic alterations. Therefore, the applicant believes that Erdafitinib treats a different patient population than currently available treatments.

We are inviting public comments on whether Erdafitinib is substantially similar to any existing technology and whether it meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis. The applicant searched the FY 2017 MedPAR Hospital Limited Data Set (LDS) for inpatient hospital claims for potential cases representing patients who may be eligible for treatment using Erdafitinib. The applicant noted that because the inpatient admission for the potential cases identified would likely be unrelated to the proposed indication for the use of Erdafitinib, it is unlikely that the administration of Erdafitinib would be initiated during an inpatient hospitalization. In addition, the applicant assumed that most hospitals would not utilize Erdafitinib for short-stay inpatient hospitalization, and the applicant therefore eliminated all identified potential cases representing inpatient hospitalizations of 3 days or fewer from its analysis. The applicant also assumed that any inpatient hospitalization of 4 days or longer would involve the daily administration of Erdafitinib and calculated the drug's costs on a case-by-case basis, multiplying the length-of-stay times the cost of the drug.

The applicant used a combination of ICD–10–CM diagnosis codes to identify these potential cases. The applicant first identified claims with one of the following ICD–10–CM diagnosis codes listed in the table below.

ICD–10–CM diagnosis code	Code description
C67.8	Malignant neoplasm of overlapping sites of bladder.
C67.9	Malignant neoplasm of bladder, unspecified.
C68.8	Malignant neoplasm of overlapping sites of urinary organs.
C68.9	Malignant neoplasm of urinary organ, unspecified.

The applicant then searched the MedPAR data file for inpatient hospital claims that also had one of the following ICD–10–CM diagnosis codes listed in the table below to identify a combination of applicable codes.

ICD–10–CM diagnosis code	Code description
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymphnodes.
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes.
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes.
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions.
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified.
C78.00	Secondary malignant neoplasm of unspecified lung.
C78.7	Secondary malignant neoplasm of unspecified lung.
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis.
C79.19	Secondary malignant neoplasm of other urinary organs.
C79.51	Secondary malignant neoplasm of bone.
C79.82	Secondary malignant neoplasm of genital organs.

Based on this search, the applicant identified 2,844 cases mapping to a wide range of MS–DRGs. The applicant identified and used in its analysis those MS–DRGs to which more than 1 percent of the total identified cases were assigned, as listed in the table below.

MS–DRG	MS–DRG title
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC.
654	Major Bladder Procedures with CC.
687	Kidney & Urinary Tract Neoplasms with CC.
686	Kidney & Urinary Tract Neoplasms with MCC.
872	Septicemia or Severe Sepsis without MV >96 Hours without MCC.
683	Renal Failure with CC.
698	Other Kidney & Urinary Tract Diagnoses with MCC.
669	Transurethral Procedures with CC.
690	Kidney & Urinary Tract Infections without MCC.
682	Renal Failure with MCC.
699	Other Kidney & Urinary Tract Diagnoses with CC.
653	Major Bladder Procedures with MCC.
853	Infectious & Parasitic Diseases with O.R. Procedure with MCC.
543	Pathological Fractures & Musculoskeletory & Connective Tissue Malignancy with CC.
948	Signs & Symptoms without MCC.
668	Transurethral Procedures with MCC.
542	Pathological Fractures & Musculoskeletory & Connective Tissue Malignacy with MCC.
657	Kidney & Ureter Procedures For Neoplasm with CC.
641	Miscellaneous Disorders of Nutrition, Metabolism, Fluids/Electrolytes without MCC.
180	Respiratory Neoplasms with MCC.
291	Heart Failure & Shock with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO).

Using 100 percent of the cases assigned to these MS–DRGs, the applicant determined an average case-weighted unstandardized charge per case of $86,302. The applicant did not remove any charges for prior therapies because the applicant indicated that the use of Erdafitinib would not replace any other therapies. The applicant standardized the charges for each case and inflated each case's charges by applying the FY 2019 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.08864 (83 FR 41722). (We note that the 2-year charge inflation factor was revised in the FY 2019 IPPS/LTCH PPS final rule correction notice. The revised factor is 1.08986 (83 FR 49844). However, we note that even when using either the revised final rule values or the corrected final rule values published in the correction notice to inflate the charges, the final inflated average case-weighted standardized charge per case for Erdafitinib would exceed the average case-weighted threshold amount.) The applicant then added the charges for the cost of Erdafitinib. To determine the charges for the cost of Erdafitinib, the applicant used the inverse of the FY 2019 IPPS/LTCH PPS final rule pharmacy national average CCR of 0.191. The applicant's reported average case-weighted threshold amount was $62,435 and its reported final inflated average case-weighted standardized charge per case was $111,713. Based on this analysis, the applicant believes Erdafitinib meets the cost criterion because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount. We are inviting public comments on whether Erdafitinib meets the cost criterion.

The applicant asserts that Erdafitinib represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to or ineligible for currently available treatments. The applicant stated that Erdafitinib provides a substantial clinical improvement for a select group of patients who have been diagnosed with locally advanced or metastatic urothelial carcinoma who have failed first-line treatment and have limited second-line treatment options, despite the recent introduction of checkpoint inhibitors. The applicant further stated that the use of Erdafitinib will be the first available treatment option specific for the subset of patients who have certain fibroblast growth factor receptor (FGFR) genetic alterations that are detected by an FDA-approved test. The applicant also believes that Erdafitinib represents a significant clinical improvement because the technology reduces mortality, decreases pain, and reduces recovery time.

To support its assertions of substantial clinical improvement, the applicant submitted the results of a Phase I dose-escalation study for the use of Erdafitinib in the target patient population for which the applicant asserts Erdafitinib would be the first available treatment option and represents a substantial clinical improvement, which is patients who had been diagnosed with advanced solid tumors for which standard curative treatment appeared no longer effective. With a sample size of 65 patients, patients received escalating oral doses of Erdafitinib ranging from 0.5 mg to 12 mg, administered continuously daily, or oral doses of Erdafitinib of 10 mg or 12 mg administered on a 7-days-on/7-days-off intermittent schedule. The study intended to identify the Recommended Phase II Dose (RP2D) and investigate the safety and pharmacodynamics of the drug. The applicant stated that the initial RP2D was considered 9 mg continuous daily dosing and 10 mg for intermitted dosing on the basis of improved tolerability.

The applicant also provided data from a multi-center, open-label Phase II study of 99 patients, ages 36 years old to 87 years old, with the median age being 68 years old, who had been diagnosed with metastatic or unresectable urothelial carcinoma that had specific FGFR alterations and were treated with a starting daily dose of Erdafitinib of 8 mg. The applicant noted the study included 87 patients who progressed after at least or more than 1 line of prior chemotherapy or within 12 months of (neo) adjuvant chemotherapy. According to the applicant, the objective response rate (ORR) measured by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 criteria was 40.4 percent (95 percent confidence interval [CI], 30.7 percent to 50.1 percent; 3.0 percent complete responses and 37.4 percent partial responses). The disease control rate (complete responses, partial responses, and stable disease) was 79.8 percent. The ORRs were similar in chemotherapy-naïve patients versus patients who progressed/relapsed after chemotherapy (41.7 percent versus 40.2 percent) and in patients who had visceral metastases versus those who did not (38.5 percent versus 47.6 percent). The median time to response was 1.4 months, and the median duration of response was 5.6

months (95 percent CI, 4.2 months to 7.2 months). The applicant noted that the results demonstrated a median progression-free survival of 5.5 months (95 percent CI, 4.2 months to 6.0 months) and a median overall survival of 13.8 months (95 percent CI, 9.8 months-not estimable). In an exploratory analysis of 22 patients previously treated with immunotherapy, the ORR was 59 percent; response to prior immunotherapy (per investigator) in these patients was 5 percent.[188] [189]

The applicant also referenced an ongoing Phase III study, but indicated that the data was not available at the time of the application's submission.

We have the following concerns with regard to whether the technology meets the substantial clinical improvement criterion. First, the applicant did not provide substantial data comparing Erdafitinib to existing therapies. Additionally, the studies that were provided were based on small sample sizes, open-labeled, and presented without a complete comparison to existing therapies. Due to the limited nature of available data, we have concerns that we may not have enough information to determine if Erdafitinib represents a substantial clinical improvement over existing technologies.

We are inviting public comments on whether Erdafitinib meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Erdafitinib or at the New Technology Town Hall meeting.

i. ERLEADA™ (Apalutamide)

Johnson & Johnson Health Care Systems Inc., on behalf of Janssen Products, LP, Inc., submitted an application for new technology add-on payments for ERLEADA™ (apalutamide) for FY 2020. ERLEADA™ received FDA approval on February 14, 2018. This oral drug is an androgen receptor inhibitor indicated for the treatment of patients who have been diagnosed with non-metastatic castration-resistant prostate cancer (nmCRPC).

Prostate cancer is the second leading cause of cancer death in men.[190] Androgens, a type of hormone that includes testosterone, can promote tumor growth. Androgen-deprivation therapy (ADT) is initially an effective way to treat prostate cancer. However, almost all men with prostate cancer eventually develop castration-resistant disease, or cancer that continues to grow despite treatment with hormone therapy or surgical castration.[191] Non-metastatic castration-resistant prostate cancer (nmCRPC) is a clinical state in which cancer has not spread to other parts of the body, but continues to grow despite treatment with ADT, either medical or surgical, that lowers testosterone levels. Delaying metastases, or extending metastasis-free survival (MFS), may delay symptomatic progression, morbidity, mortality, and healthcare resource utilization. According to the applicant, nearly all men who die from prostate cancer have antecedent metastases to bone or other sites. ERLEADA™ blocks the effect of androgens on the tumor in order to delay metastases, a major cause of complications and death among men with prostate cancer. Prior to ERLEADA™, there were no FDA-approved treatments for nmCRPC to delay the onset of metastatic castration-resistant prostate cancer (mCRPC).[192] The U.S. incidence of nmCRPC is estimated to be 50,000 to 60,000 cases per year.[193]

With respect to the newness criterion, ERLEADA™ (apalutamide) was granted Fast Track and Priority Review designations under FDA's expedited programs, and received FDA approval on February 14, 2018 for the treatment of patients who have been diagnosed with non-metastatic castration-resistant prostate cancer. Currently, there are no ICD–10–PCS procedure codes to uniquely identify the administration of ERLEADA™. We note that the applicant submitted a request for approval for a unique ICD–10–PCS code for the administration of ERLEADA™ beginning in FY 2020.

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant maintained that ERLEADA™ is new because it was the first drug approved by the FDA with its mechanism of action. Specifically, ERLEADA™ is an androgen receptor (AR) inhibitor that binds directly to the ligand-binding domain of the AR. It has a trifold mechanism of action. Apalutamide inhibits AR nuclear translocation, inhibits DNA binding, and impedes AR-mediated transcription, which together inhibit tumor cell growth.[194] According to the applicant, in non-clinical studies, apalutamide administration caused decreased tumor cell proliferation and increased apoptosis leading to decreased tumor volume in mouse xenograft models of prostate cancer. Furthermore, the applicant asserted that in additional non-clinical studies, apalutamide was shown to have a higher binding affinity to the androgen receptor than bicalutamide (CASODEX), a first-generation anti-androgen that has been used in clinical practice for the treatment of nmCRPC. However, the applicant noted that bicalutamide is not FDA-approved for this indication nor is there Phase III data available on its use in this population. In addition, according to the applicant, apalutamide has a different mechanism of action than bicalutamide because it does not show antagonist-to-antagonist switch like bicalutamide.

With regard to the second criterion, whether a product is assigned to the same or different MS–DRG, the applicant noted that patients who may be eligible to receive treatment involving ERLEADA™ in the inpatient setting will likely be hospitalized due to other conditions. Therefore, the applicant explained that potential cases eligible to receive treatment involving ERLEADA™ are likely to be assigned to a wide variety of MS–DRGs, and

[188] Nishina, T., Takahashi, S., Iwasawa, R., et al., ''Safety, pharmacokinetic, and pharmacodynamics of erdafitinib, a pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor, in patients with advanced or refractory solid tumors,'' *Invest New Drugs,* 2018, vol. 36, pp. 424–434.

[189] Tabernero, J., Bahleda, R., Dienstmann, R., et al., ''Phase I Dose-Escalation Study of JNJ–42756493, an Oral Pan–Fibroblast Growth Factor Receptor Inhibitor, in Patients With Advanced Solid Tumors,'' *J Clin Onc,* Vol. 33(30), October 20, 2015, pp. 3001–3008.

[190] American Cancer Society. *https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2019.html.*

[191] Dai, C., Heemers, H., Sharifi, N., ''Androgen signaling in prostate cancer,'' Cold Spring Harb Perspect Med, 2017, vol. 7(9), pp. a030452.

[192] Center for Drug Evaluation and Research. NDA/BLA Multi-Disciplinary Review and Evaluation (Summary Review, Office Director, Cross Discipline Team Leader Review, Clinical Review, Non-Clinical Review, Statistical Review and Clinical Pharmacology Review) NDA 210951—ERLEADA (apalutamide)—Reference ID: 4221387. Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210951Orig1s000MultidisciplineR.pdf.* Published March 19, 2018.

[193] Beaver, Julia A., Kluetz, Paul, Pazdur, Richard, ''Metastasis-free Survival—A New End Point in Prostate Cancer Trials,'' 2018, *N Eng J of Med,* vol. 378, pp. 2458–2460, 10.1056/NEJMp1805966.

[194] Clegg, N.J., Wongvipat, J., Joseph, J.D., et al., ''ARN–509: a novel antiandrogen for prostate cancer treatment,'' *Cancer Res,* 2012, vol. 72(6), pp. 1494–503.

ERLEADA™ is similar to existing technologies in this respect.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant maintained that ERLEADA™ was the first FDA-approved treatment option for patients who have been diagnosed with nmCRPC. According to the applicant, there are a number of therapies currently available for patients who have been diagnosed with mCRPC, including chemotherapy, continuous ADT, immunotherapy, radiation therapy, radiopharmaceutical therapy, and androgen pathway treatments, including secondary hormonal therapies and supportive care. However, prior to ERLEADA™, there were no FDA-approved treatment options for patients who have been diagnosed with nmCRPC to delay the onset of mCRPC. Therefore, according to the applicant, ERLEADA™ provides a treatment option to patients who have been diagnosed with a stage of prostate cancer that previously had no other approved treatment options available, and the standard approach was ''watch and wait/observation.'' The applicant stated that both the National Comprehensive Cancer Network® (NCCN®) guidelines for prostate cancer and American Urological Association (AUA) guidelines for castration-resistant prostate cancer note the limited treatment options for nmCRPC as compared to mCRPC. The applicant pointed out that apalutamide is highly recommended, as one of the two treatments with a Category 1 recommendation included in the NCCN® guidelines and standard treatment options for asymptomatic nmCRPC based on evidence level Grade A in the AUA guidelines.[195] [196] Therefore, the applicant posited that ERLEADA™ involves the treatment of a new patient population because it is a new treatment option for patients who have been diagnosed with nmCRPC and have limited available treatment options.

As summarized above, the applicant maintained that ERLEADA™ meets the newness criterion and is not substantially similar to existing technologies because it has a unique mechanism of action and offers an effective treatment option to a new patient population with limited available treatment options. We are inviting public comments on whether ERLEADA™ meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. In order to identify the range of MS–DRGs to which cases representing potential patients who may be eligible for treatment using ERLEADA™ may map, the applicant identified cases that would be eligible for use of ERLEADA™ by the presence of two ICD–10–CM diagnosis code combinations: C61 (Malignant neoplasm of prostate) in combination with R97.21 (Rising PSA following treatment for malignant neoplasm of prostate); or C61 in combination with Z19.2 (Hormone resistant malignancy status). The applicant searched the FY 2017 MedPAR final rule file (claims from FY 2015) for claims with the presence of the two code combinations above. Cases identified mapped to a wide variety of MS–DRGs. The applicant eliminated all hospital stays of fewer than 4 days from its analysis because of its assumption that most hospitals would not provide ERLEADA™ for short-stay inpatients. The applicant also assumed that any hospital stay 4 days or longer would involve the daily provision of ERLEADA™. This resulted in 493 cases across 152 MS–DRGs, with approximately 33 percent of all cases mapping to the following 9 MS–DRGs: MS–DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC); MS–DRG 543 (Pathological Fractures and Musculoskeletal and Connective Tissue Malignancy with CC); MS–DRG 683 (Renal Failure with CC); MS–DRG 723 (Malignancy, Male Reproductive System with CC); MS–DRG 722 (Malignancy, Male Reproductive System with MCC); MS–DRG 698 (Other Kidney and Urinary Tract Diagnoses with MCC); MS–DRG 699 (Other Kidney and Urinary Tract Diagnoses with CC); MS–DRG 682 (Renal Failure with MCC); and MS–DRG 948 (Signs and Symptoms without MCC).

For the 493 identified cases, the average case-weighted unstandardized charge per case was $66,559. The applicant then standardized the charges using the FY 2017 IPPS/LTCH PPS final rule Impact file. Because ERLEADA™ would not replace any other therapies occurring during the inpatient stay, the applicant did not remove any charges for the current treatment. The applicant then applied the 2-year inflation factor of 8.59 percent (1.085868) published in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41718) to inflate the charges from FY 2017 to FY 2019. We note that the inflation factors were revised in the FY 2019 IPPS/LTCH PPS final rule correction notice. The corrected final 2-year inflation factor is 1.08986 (83 FR 49844). The applicant converted the costs of ERLEADA™ to charges using the inverse of the FY 2019 IPPS/LTCH PPS final rule pharmacy national average CCR of 0.191 (83 FR 41273) to include the charges in its estimate. Based on the FY 2019 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case-weighted threshold amount was $52,362. The average case-weighted standardized charge per case was $76,901. Because the average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

The applicant submitted an additional cost analysis including hospital stays shorter than 4 days to demonstrate that ERLEADA™ also meets the cost criterion using all discharges in the analysis, regardless of length of stay. While the applicant maintained that ERLEADA™ is unlikely to be administered by the hospital for inpatient stays fewer than 4 days, the applicant demonstrated that the average case-weighted standardized charge per case ($57,150) continues to exceed the average case-weighted threshold amount ($50,225) using all discharges (932 cases).

We note that the applicant used the proposed rule values to inflate the standardized charges above. However, we further note that even when using either the final rule values or the corrected final rule values to inflate the charges, the average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in each analysis. We are inviting public comments on whether ERLEADA™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that ERLEADA™ represents a substantial clinical improvement because: (1) The technology offers a treatment option for a patient population previously ineligible for treatments, because ERLEADA™ is the first FDA-approved treatment for patients who have been diagnosed with nmCRPC; and (2) use of the technology significantly improves clinical outcomes for a patient population because ERLEADA™ was shown to significantly improve a number of clinical outcomes in the

[195] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Prostate Cancer (Version 4.2018). National Comprehensive Cancer Network. Available at: *www.nccn.org.* Published August 15, 2018.

[196] Lowrance, W.T., Murad, M.H., Oh, W.K., et al., ''Castration-Resistant Prostate Cancer: AUA Guideline Amendment 2018,'' *J Urol,* 2018, pii: S0022–5347(18)43671–3.

randomized Phase III SPARTAN trial,[197] including significant improvement in metastasis-free survival (MFS).

First, the applicant stated that there were no FDA-approved treatments to delay metastasis for patients who have been diagnosed with nmCRPC, a small but important clinical state within the spectrum of prostate cancer, prior to the FDA approval of ERLEADA™. The applicant emphasized that until the FDA approved the use of ERLEADA™, Medicare patients who have been diagnosed with nmCRPC had extremely limited treatment options, and the standard approach was ''watch and wait/observation.'' The applicant asserted that ERLEADA™ offers a promising new treatment option and has been shown to improve MFS in a Phase III trial [198] with a demonstrated safety and tolerability profile and no negative impact to health-related quality of life based on patient-reported outcomes. Therefore, the applicant stated that the ''robust results'' of the clinical trial demonstrate that ERLEADA™ is a substantial clinical improvement over existing technologies because it provides an effective treatment option for a patient population previously ineligible for treatments.

Second, the applicant maintained that ERLEADA™ is a substantial clinical improvement because ERLEADA™ was shown to significantly improve a number of clinical outcomes, most notably MFS. Metastases are a major cause of complications and death among men with prostate cancer. Therefore, according to the applicant, delaying metastases may delay symptomatic progression, morbidity, mortality, and healthcare resource utilization. ERLEADA™ was approved by the FDA based on a prostate cancer trial using the primary endpoint of MFS, with overall survival used as a secondary endpoint.

The SPARTAN trial was a randomized, double-blind, placebo-controlled, Phase III trial which included men who had been diagnosed with nmCRPC and a prostate-specific antigen doubling time of 10 months or less. Patients were randomly assigned, in a 2:1 ratio, to receive apalutamide (240 mg per day) or placebo. A total of 1,207 men underwent randomization (806 to the apalutamide group and 401 to the placebo group). All of the patients continued to receive androgen-deprivation therapy. The primary end point of MFS was defined as the time from randomization to the first detection of distant metastasis on imaging or death. The study team calculated that a sample of 1,200 patients with 372 primary end-point events would provide the trial with 90 percent power to detect a hazard ratio for metastasis or death in the apalutamide group versus the placebo group of 0.70, at a two-sided significance level of 0.05. The Kaplan–Meier method was used to estimate medians for each trial group. The primary statistical method of comparison for time-to-event end points was a log-rank test with stratification according to the pre-specified factors. Cox proportional-hazards models were used to estimate the hazard ratios and 95 percent confidence intervals.

According to the applicant, results of the primary endpoint analysis for MFS were both statistically significant and clinically meaningful. Median MFS was 40.5 months in the apalutamide group as compared with 16.2 months in the placebo group (hazard ratio [HR]=0.28; 95 percent confidence interval [CI]: 0.23, 0.35; P<0.0001). In other words, ERLEADA™ significantly prolonged MFS by 2 years in men who had been diagnosed with nmCRPC. In a multi-variate analysis, treatment with ERLEADA™ was an independent predictor for longer MFS (HR: 0.26; 95 percent CI: 0.21–0.32; P<0.0001). The treatment effect of ERLEADA™ on MFS was consistently favorable across pre-specified subgroups, including patients with Prostate Specific Antigen doubling time (PSADT) of less than 6 months versus more than 6 months (short PSA doubling time is a predictor of metastasis), use of bone-sparing agents, and local-regional disease.

Additionally, the applicant stated that the validity of the primary endpoint results is supported by improvements in all secondary endpoints, with significant improvement observed in time to metastasis, progression-free survival (PFS), and time to symptomatic progression (all P<0.001) for ERLEADA™ compared to placebo.

According to the applicant, treatment with ERLEADA™ significantly extended time to metastasis by almost 2 years (40.5 months versus 16.6 months, P<0.001). In addition, time to bone metastasis and nodal metastasis in particular were both significantly longer (P<0.0001) in the ERLEADA™ group compared to the placebo group.

According to the applicant, ERLEADA™ was also associated with a significant improvement in the secondary endpoint of PFS, at 40.5 months for the ERLEADA™ group versus 14.7 months for the placebo group (P<0.001). In a multi-variate analysis of patients treated in the SPARTAN study, treatment with ERLEADA™ was an independent predictor for longer time to symptomatic progression (reached versus not reached; P<0.001).

The applicant also included the results of additional secondary endpoints for CMS consideration as evidence of substantial clinical improvement, including a suggested overall survival (OS) benefit; demonstrated safety profile; maintained quality of life; and decreased prostate specific antigen (PSA) levels.

While OS data were not mature at the time of final MFS analysis (only 24 percent of the required number of OS events were available for analysis), the applicant asserted that OS results suggested a benefit of treatment using ERLEADA™ as compared to placebo. The applicant explained that, according to a statistical analysis model correlating the proportion of variability of OS attributable to the variability of MFS, patients who developed metastases at 6, 9, and 12 months had significantly shorter median OS compared with those patients without metastasis.

The applicant also stated that treatment using ERLEADA™ provides an effective option with a demonstrated safety profile and tolerability for patients who have been diagnosed with nmCRPC. The safety of the use of ERLEADA™ was assessed in the SPARTAN trial, and adverse events (AEs) that occurred at ≥15 percent in either group included: Fatigue, hypertension, rash, diarrhea, nausea, weight loss, arthralgia, and falls. The applicant asserted that in considering the risks and benefits of treatment involving the use of ERLEADA™ for patients who have been diagnosed with nmCRPC, the FDA noted that there were no FDA-approved treatments for the indication and that ERLEADA™ had a favorable risk-benefit profile.

Next, the applicant stated that the use of ERLEADA™ also has a substantial clinical improvement benefit of maintaining quality of life. According to the applicant, patients who have been diagnosed with nmCRPC are generally asymptomatic, so it is a positive outcome if the addition of a therapy does not cause degradation of health-related quality of life. The applicant maintained that in asymptomatic men who have been diagnosed with high-risk nmCRPC, health-related quality of life (HRQOL) was maintained after

[197] Smith, M.R., et al., ''Apalutamide Treatment and Metastasis-free Survival in Prostate Cancer,'' *N Engl J Med,* 2018, vol. 12;378(15), pp. 1408–1418.

[198] Ibid.

initiation of the use of ERLEADA™.[199] According to the applicant, patient-reported outcomes using the Functional Assessment of Cancer Therapy-Prostate [FACT–P] questionnaire and European Quality of Life-5 Dimensions-3 Levels [EQ–5D–3L] questionnaire results indicated that patients who received treatment involving ERLEADA™ maintained stable overall HRQOL outcomes over time from both treatment groups.

Additionally, the applicant discussed prostate specific antigen (PSA) outcomes as another secondary result demonstrating substantial clinical improvement. PSA, a protein produced by the prostate gland, is often present at elevated levels in men who have been diagnosed with prostate cancer and PSA tests are used to monitor the progression of the disease. According to the applicant, at 12 weeks after randomization, the median PSA level had decreased by 89.7 percent in the ERLEADA™ group versus an increase of 40.2 percent in the placebo group. In an exploratory analysis performed by the applicant of patients treated in the SPARTAN study, the use of ERLEADA™ decreased the risk of PSA progression by 94 percent compared with the patients in the placebo group (not reached vs 3.71 months; HR: 0.064; 95 percent CI: 0.052–0.080; P<0.0001). Overall, a ≥90 percent maximum decline in PSA from baseline at any time during the study was reported in 66 percent of the patients in the ERLEADA™ group and 1 percent of the patients in the placebo group, according to the applicant. The applicant noted that increase in time to PSA progression is relevant from a clinical standpoint for clinicians and patients alike because PSA monitoring, rather than the use of regularly scheduled surveillance imaging, as was the case with SPARTAN, is often the most practical method of screening for progression of nmCRPC.

We have the following concerns regarding the applicant's assertions of substantial clinical improvement:

- Regarding the SPARTAN trial design, we are concerned that the study enrollment may not be representative of the U.S. population considering that North American enrollment was only 35 percent of patients overall, and only approximately 6 percent of enrolled patients were black. Underrepresentation of black patients is of particular concern considering that, in the United States, African-American patients are disproportionately affected by prostate cancer. According to the CDC,[200] the rate of new prostate cancers by race is 158.3 per 100,000 men for African-Americans, compared to 90.2 for whites, 78.8 for Hispanics, 51.0 for Asian/Pacific Islanders, and 49.6 for American Indians/Alaska Natives. We are concerned that, based on an exploratory subgroup analysis performed by the applicant, black patients may not have performed better in the treatment group; while the hazard ratio of 0.63 (95 percent confidence interval: 0.23, 1.72) suggests a benefit to the group treated with ERLEADA™, the median MFS for this subgroup was reported as shorter for the ERLEADA™ group at 25.8 months than for the placebo group, at 36.8 months.[201] Additionally, we note that 23 percent of the patients in the SPARTAN trial did not have definitive local therapy at baseline for their diagnosis of prostate cancer, which is accepted standard-of-care in the United States.

In response to this concern about low North American enrollment and subgroup underrepresentation, the applicant submitted additional information claiming a consistent treatment effect across all subpopulations and regions. The applicant also pointed to the low hazard ratio for the subgroup of black patients as support for the benefit of the use of ERLEADA™. We welcome additional information and public comments on whether the SPARTAN trial results are generalizable to the U.S. population, and in particular, African-American patients.

- We also note regarding the SPARTAN trial that a total of 7.0 percent of the patients in the ERLEADA™ group and 10.6 percent of the patients in the placebo group withdrew consent from the trial. Additional explanation from the applicant of how those that withdrew were considered in the analysis, and whether there was any analysis of potential impact of withdrawals on the study results would be helpful.
- We also have concerns about the primary endpoint used for the SPARTAN trial, MFS. The applicant explained that MFS was determined to be a reasonable end point for patients who have been diagnosed with nmCRPC because of the difficulty in using OS as a primary endpoint; multiple drugs can be used sequentially for advanced disease, necessitating larger and longer trials and potentially confounding interpretation of results if attempting to prove that a prostate cancer drug lengthens OS. Nevertheless, because MFS is not identical to OS and data on OS was not mature at the time of the study's results, we note that it may be difficult to conclude based on the current data whether the use of ERLEADA™ improves OS.

To address this concern, the applicant submitted additional information on MFS as a surrogate clinical endpoint for OS, including a recent study by the International Clinical Endpoints for Cancer of the Prostate (ICECaP) Working Group showing a correlation between MFS and OS in several prostate cancer studies.[202] The applicant explained that based on review of 19 randomized, controlled trials evaluating 21 study units in 12,712 men with localized prostate cancer, the correlation between OS and MFS was 0.91 (95 percent CI: 0.91–0.91) at the patient level, as measured by Kendall's τ. To demonstrate that MFS is closely linked with OS, the applicant cited a retrospective analysis of electronic health record database for patients who have been diagnosed with nmCRPC in which MFS independently predicted mortality risk; patients developing metastasis within 1 year had 4.4-fold greater risk for mortality (95 percent CI: 2.2–8.8) than those who remained metastasis-free at year 3.[203] The applicant also reiterated that a significant positive correlation between MFS and OS was observed in the SPARTAN trial (Pearson's correlation coefficient=0.66; Spearman's correlation coefficient=0.62, P<0.0001; and Kendall τ statistic=0.52, parametric Fleischer's statistical model correlation coefficient of 0.69 (standard error, 0.002; 95 percent CI: 0.69–0.70)).

We are inviting public comments on whether ERLEADA™ meets the substantial clinical improvement criterion for patients who have been

[199] Saad, F., et al., ''Effect of apalutamide on health-related quality of life in patients with non-metastatic castration-resistant prostate cancer: an analysis of the SPARTAN randomized, placebo-controlled, phase 3 trial,'' *Lancet Oncology,* 2018 Oct; Epub 2018 Sep 10.

[200] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute, U.S. Cancer Statistics Working Group, U.S. Cancer Statistics Data Visualizations Tool, based on November 2017 submission data (1999–2015), Availavle at: *www.cdc.gov/cancer/dataviz,* June 2018.

[201] Smith, M.R., et al., ''Apalutamide Treatment and Metastasis-free Survival in Prostate Cancer,'' *N Engl J Med,* 2018, vol. 12;378(15), pp. 1408–1418.

[202] ICECaP Working Group, Sweeney, C., Nakabayashi, M., et al., ''The development of intermediate clinical endpoints in cancer of the prostate (ICECaP)'', *J Natl Cancer Inst,* 2015, vol. 107(12), pp. djv261.

[203] Li S, Ding Z, Lin J.H., et al., ''Association of prostate-specific antigen (PSA) trajectories with risk for metastasis and mortality in nonmetastatic castration-resistant prostate cancer (nmCRPC),'' Abstract presented at: 2018 Genitorurinary Cancers Symposium, February 8–10, 2018, San Francisco, CA.

diagnosed with nmCRPC. We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ERLEADA™ or at the New Technology Town Hall meeting.

j. SPRAVATO (Esketamine)

Johnson & Johnson Health Care Systems, Inc., on behalf of Janssen Pharmaceuticals, Inc., submitted an application for new technology add-on payments for SPRAVATO (Esketamine) nasal spray for FY 2020. The FDA indication for SPRAVATO is treatment-resistant depression (TRD).

According to the applicant, major depressive disorder affects nearly 300 million people of all ages globally and is the leading cause of disability worldwide. People with major depressive disorder (MDD) suffer from a serious, biologically-based disease which has a significant negative impact on all aspects of life, including quality of life and function.[204] Although currently available anti-depressants are effective for many of these patients, approximately one-third do not respond to treatment.[205] Patients who have not responded to at least two different anti-depressant treatments of adequate dose and duration for their current depressive episode are considered to have been diagnosed with TRD. MDD in older age is marked by lower response and remission rates, greater disability and functional decline, decreased quality of life, and greater mortality from suicide.[206] [207] [208]

According to the applicant, currently available pharmacologic treatments for depression include Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin–norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs), tricyclic anti-depressants (TCAs), other atypical anti-depressants, and adjunctive atypical antipsychotics. In addition to SPRAVATO, the only pharmacologic treatment currently approved for treatment-resistant depression is a combination of two drugs: An antipsychotic and an SSRI (fluoxetine/olanzapine combination). Currently available non-pharmacological medical treatments include electroconvulsive therapy, vagal nerve stimulation, deep brain stimulation (DBS), transcranial direct current stimulation (tDCS), and repetitive transcranial magnetic stimulation (rTMS).

According to the applicant, SPRAVATO is a non-competitive, subtype non-selective, activity-dependent glutamate receptor modulator. The applicant indicates that SPRAVATO works through increased glutamate release resulting in downstream neurotrophic signaling facilitating synaptic plasticity, thereby bringing about rapid and sustained improvement in people who have been diagnosed with TRD. The applicant explained that, through glutamate receptor modulation, SPRAVATO helps to restore connections between brain cells in people who have been diagnosed with TRD.[209]

According to the applicant, the nasal spray device is a single-use device that delivers a total of 28 mg of SPRAVATO in two sprays (one spray per nostril). The applicant has approved dosages of 56 mg (two devices) or 84 mg (three devices), with a 28 mg (one device) available for patients 65 years old and older. The treatment session consists of healthcare supervision of the patient's self-administration of SPRAVATO HCL to ensure proper usage and post-administration observation to ensure patient stability. Specifically, clinicians will need to monitor blood pressure and mental status changes. The applicant states that monitoring will be required at every administration session.

With respect to the newness criterion, the applicant submitted a New Drug Application (NDA) for SPRAVATO HCL Nasal Spray based on a recently completed Phase III clinical development program for treatment-resistant depression. According to the applicant, SPRAVATO was granted a Breakthrough Therapy designation in 2013. SPRAVATO HCL Nasal Spray was approved by the FDA with an effective date of March 5, 2019. Currently there are no ICD–10–PCS procedure codes to uniquely identify the administration of SPRAVATO HCL Nasal Spray. The applicant has submitted a request for approval for a unique ICD–10–PCS procedure code to specifically identify cases involving the administration of SPRAVATO HCL, beginning in FY 2020.

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action, the applicant asserts that SPRAVATO has a unique mechanism of action. The applicant stated that SPRAVATO's unique mechanism of action is the first new approach in 30 years for the treatment of major depressive disorder, including treatment-resistant depression.[210] [211] According to the applicant, unlike existing approved anti-depressant pharmacotherapies, SPRAVATO's anti-depressant activity does not primarily modulate monoamine systems (norepinephrine, serotonin, or dopamine). The applicant asserts that SPRAVATO restores connections between brain cells in people with treatment-resistant depression through glutamate receptor modulation, which results in downstream neurotropic signaling.[212]

With regard to the second criterion, whether the technology is assigned to the same or different MS–DRG, the applicant asserts that it is likely that potential cases representing patients who may be eligible for treatment involving the use of SPRAVATO HCL Nasal Spray would be assigned to the same MS–DRGs as patients who receive treatment involving currently available anti-depressants (AD).

With regard to the third criterion, whether the technology treats the same or a similar disease or the same or similar patient population, the applicant asserts that potential patients who may be eligible to receive treatment involving SPRAVATO will be comprised of a subset of patients who are receiving treatment involving currently available anti-depressants. The applicant did not specifically

[204] World Health Organization. (2018, March). Depression. Available at: *http://www.who.int/mediacentre/factsheets/fs369/en/.*

[205] National Institute of Mental Health. (2006, January). Questions and Answers about the NIMH Sequenced Treatment Alternatives to Relieve Depression (STAR*D)—Background. Available at: *https://www.nimh.nih.gov/funding/clinical-research/practical/stard/backgroundstudy.shtml.*

[206] Manthorpe, J., & Iliffe, S., ''Suicide in later life: Public health and practitioner perspectives,'' *International Journal of Geriatric Psychiatry,* 2010, vol. 25(12), pp. 1230–1238.

[207] Lenze, E., Sheffrin, M., Driscoll, H., Mulsant, B., Pollock, B., Dew, M., Reynolds, C., ''Incomplete response in late-life depression: Getting to remission,'' *Dialogues in Clinical Neuroscience,* 2008, vol. 10(4), pp. 419–430.

[208] Alexopoulos, G., & Kelly, R., ''Research advances in geriatric depression,'' *World Psychiatry,* 2009, vol. *8*(3), pp. 140–149.

[209] Sanacora, G., et. al., ''Targeting the Glutamatergic System to Develop Novel, Improved Therapeutics for Mood Disorders,'' Nat Rev Drug Discov., 2008, pp. 426–437.

[210] Duman, R. (2018). Ketamine and rapid-acting anti-depressants: a new era in the battle against depression and suicide. F1000Research, 7, 659. doi:10.12688/f1000research.14344.1.

[211] Dubovsky, S., ''What Is New about New Anti-depressants?,'' *Psychotherapy and Psychosomatics,* 2018, vol. 87(3), pp. 129–139, doi:10.1159/000488945.

[212] Sanacora, G., et al., ''Targeting the Glutamatergic System to Develop Novel, Improved Therapeutics for Mood Disorders,'' Nat Rev Drug Discov., 2008, pp. 426–437.

address the application of this criterion to SPRAVATO.

We are inviting public comments on whether SPRAVATO is substantially similar to any existing technologies and whether it meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. To identify cases eligible for SPRAVATO, the applicant searched the FY 2017 MedPAR data file for claims with the presence of one of the following ICD–10–CM diagnosis codes: F33 (Major depressive disorder, recurrent), F33.2 (Major depressive disorder, recurrent severe without psychotic features), F33.3 (Major depressive disorder, recurrent, severe with psychotic symptoms), and F33.9 (Major depressive disorder, recurrent, unspecified). Claims from the FY 2017 MedPAR data file with the presence of one of these ICD–10–CM diagnosis codes mapped to a wide variety of MS–DRGs. The applicant excluded claims if they had one or more diagnoses from the following list: (1) Aneurysmal vascular disease; (2) intracerebral hemorrhage; (3) dementia; (4) hyperthyroidism; (5) pulmonary insufficiency; (6) uncontrolled brady- or tachyarrhythmias; (7) history of brain injury; (8) hypertensive; (9) encephalopathy; (10) other conditions associated with increased intracranial pressure; and (10) pregnancy. The applicant believed that these conditions would preclude the use of SPRAVATO HCL. The applicant also assumed that hospitals would not allow administration of SPRAVATO HCL for short-stay inpatient hospitalizations and, therefore, excluded all hospitalizations of fewer than 5 days. The applicant assumed that patients would be allowed to administer their first dose on the 5th day and every 7 days thereafter. Lastly, the applicant assumed that, based on clinical data, patients would use 2.5 spray devices per treatment, once a week.

After applying the inclusion and exclusion criteria described above, the applicant identified a total of 3,437 potential cases mapping to 439 MS–DRGs, with approximately 54.7 percent of cases mapping to MS–DRGs 885 (Psychoses), 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC), 917 (Poisoning & Toxic Effects of Drugs with MCC), 897 (Alcohol/Drug Abuse or Dependence without Rehabilitation Therapy without MCC), 291 (Heart Failure & Shock with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO)), 918 (Poisoning & Toxic Effects of Drugs without MCC), 190 (Chronic Obstructive Pulmonary Disease with MCC), 853 (Infectious & Parasitic Diseases with O.R. Procedure with MCC), 683 (Renal Failure with CC), and 682 (Renal Failure with MCC). The applicant further defined the potential cases representing patients who may be eligible for treatment involving the use of SPRAVATO HCL in the cost criterion analysis by reducing the number of cases in each MS–DRG by one-third due to clinical data indicating that approximately one-third of patients who have been diagnosed with MDD also have been diagnosed with TRD.[213] [214]

The applicant calculated the average case-weighted unstandardized charge per case to be $73,119. Because the use of SPRAVATO HCL is not expected to replace prior treatments, the applicant did not remove any charges for the prior technology. The applicant then standardized the charges and applied a 2-year inflation factor of 1.08986 obtained from the FY 2019 IPPS/LTCH PPS final rule correction notice (83 FR 49844). The applicant then added charges for the new technology to the inflated average case-weighted standardized charges per case. No other related charges were added to the cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $74,738 and an average case-weighted threshold amount of $48,864. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the technology met the cost criterion.

With regard to the analysis above, we are concerned whether it is appropriate to reduce the number of cases to one-third of the total potential cases identified. While the supporting statistical data provided by the applicant suggest that one-third of patients who have been diagnosed with MDD often also receive diagnoses of TRD, it is unclear which cases representing patients should be removed. It is possible that patients who have been diagnosed with MDD are covered by all 439 MS–DRGs, but patients who have been diagnosed with TRD only exist in a certain subset of these same MS–DRGs. Further, those patients who have been diagnosed with TRD could account for the most costly of patients who have been diagnosed with MDD. Ultimately, without further evidence, we may not be able to verify that the assumption that patients who have been diagnosed with TRD comprise one-third of the identified cases representing patients who have been diagnosed with MDD and are evenly distributed across all of the MS–DRG identified cases is appropriate. We are inviting public comments on this issue and whether the SPRAVATO HCL Nasal Spray meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that SPRAVATO HCL Nasal Spray represents a substantial clinical improvement over existing treatments because it provides a treatment option for a patient population that failed available treatments and who have shown inadequate response to at least two anti-depressants in their current episode of MDD.[215] According to the applicant, in addition to SPRAVATO HCL, there is currently only one other pharmacotherapy used for the treatment for diagnoses of TRD that is approved by the FDA (Symbyax®, a fluoxetine-olanzapine combination), but its use is limited by tolerability concerns.[216] In support of its assertions of substantial clinical improvement, the applicant provided several studies regarding SPRAVATO HCL.

The first study is a Phase II, double-blind, doubly-randomized, placebo-controlled, multi-center study in adults aged 20 years old to 64 years old.[217] This study consisted of the following four phases: The screening, double-blind treatment, the optional open-label treatment, and post-treatment follow-up. During the treatment phase, two periods of treatment occurred between the 1st and the 8th day and the 8th and the 15th day. At the beginning of first treatment period, participants were randomized 3:1:1:1 to an intranasal placebo, SPRAVATO HCL 28 mg, 56 mg, or 84 mg twice weekly, respectively. During the second treatment period,

[213] National Institute of Mental Health. (2006, January). Questions and Answers about the NIMH Sequenced Treatment Alternatives to Relieve Depression (STAR*D)—Background. Available at: *https://www.nimh.nih.gov/funding/clinical-research/practical/stard/backgroundstudy.shtml.*

[214] Rush, A.J., Trivedi, M., Wisniewski, S., Nierenberg, A., Steward, J., Warden, D., Fava, M., ''Acute and Longer-term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR*D report,'' *American Journal of Psychiatry,* 2006, vol, 163(11), pp. 1905–1917.

[215] Rush, A.J., Trivedi, M., Wisniewski, S., Nierenberg, A., Steward, J., Warden, D., Fava, M., ''Acute and Longer-term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR*D report,'' *American Journal of Psychiatry,* 2006, vol. 163(11), pp. 1905–1917.

[216] Cristancho, M., & Thase, M, ''Drug safety evaluation of olanzapine/fluoxetine combination,'' Expert Opinion on Drug Safety, 2014, vol. 13(8), pp. 1133–1141.

[217] Daly, E., Singh, J., Fedgchin, M., Cooper, K., Lim, P., Shelton, R., Drevets, W., ''Efficacy and Safety of Intranasal Esketamine Adjunctive to Oral Anti-depressant Therapy in Treatment-Resistant Depression,'' *JAMA Psychiatry,* 2018, vol. 75(2), pp. 139–148.

patients who were initially randomized to treatment groups remained on the treatment regimen until the 15th day. Patients initially assigned to the placebo group and who had moderate to severe symptoms (as measured by the 16-item quick inventory of depressive symptomatology-self report total score) were re-randomized 1:1:1:1 to placebo, SPRAVATO HCL 28 mg, 56 mg, or 84 mg twice weekly groups, respectively.

Of the 126 patients screened, 67 were randomized at the beginning of the first treatment period, with 33 patients receiving placebo, 11 patients receiving 28 mg of SPRAVATO HCL, 11 patients receiving 56 mg of SPRAVATO HCL, and 12 patients receiving 84 mg of SPRAVATO HCL in dosages. At the beginning of the second treatment period, those in the treated group remained on the same treatment regimen, while the 33 placebo patients were re-randomized. Of the placebo group in the first treatment period, 6 patients were added to the 4 who remained on placebo, 8 patients received 28 mg of SPRAVATO HCL, 9 patients received 56 mg of SPRAVATO HCL, and 5 patients received 84 mg SPRAVATO HCL in dosages. Of the 67 respondents randomized, 63 (94 percent) completed the first treatment phase and 60 (90 percent) completed the first and second treatment phases. During both treatment phases patients were assessed at baseline, 2 hours, 24 hours, and at the study period endpoints for the Montgomery-Asberg Depression Rating Scale (MADRS) score, Clinical Global Impression of Severity scale score, adverse events and other safety assessments including the Clinician Administered Dissociative States Scale (CADSS). The primary efficacy endpoint, change from baseline to endpoint in MADRS total score, was analyzed using the analysis of covariance model including treatment and country as factors and period baseline MADRS total score as a covariate.[218]

At the end of the first treatment period, the least square mean change (standard error) for the placebo group was −4.9 (1.74). As compared to the placebo, the least square mean difference from placebo (standard error) for the SPRAVATO HCL treatment groups was −5.0 (2.99) for 28 mg of SPRAVATO HCL in dosage, −7.6 (2.91) for 56 mg of SPRAVATO HCL in dosage, and −10.5 (2.79) for 84 mg of SPRAVATO HCL in dosage; these differences were statistically significant at or beyond $p<0.05$. Similar differences were seen at 2 hours and 24 hours for these groups with the only non-significant difference occurring for 56 mg of SPRAVATO HCL in dosage at 2 hours as compared to baseline. At the end of the second treatment period, the least square mean change (standard error) for the placebo group was −4.5 (2.92), for the SPRAVATO HCL-treated groups was −3.1 (2.99) from the placebo for 28 mg of SPRAVATO HCL in dosage, −4.4 (3.06) from the placebo for 56 mg of SPRAVATO HCL in dosage, and −6.9 (3.41) from the placebo for 84 mg of SPRAVATO HCL in dosage. Only the 84 mg of SPRAVATO HCL dosage difference from the mean was statistically significant ($p<.05$). When the results from the first and second treatment periods were pooled, all three groups had statistically significant differences from the placebo. Based on these results, the applicant asserts that all three SPRAVATO HCL treatment groups were superior to the placebo.

When considering the safety profile of the use of SPRAVATO HCL, the study reports that 3 (5 percent) of the treated patients and 1 (2 percent) open-label patient experienced adverse events leading to discontinuation (syncope, headache, dissociative syndrome, ectopic pregnancy). There was a noted dose response for the adverse events of dizziness and nausea only. Most of the treated patients experienced transient elevations in blood pressure and heart rate on dosing days, as well as perceptual changes and/or dissociate symptoms (as measured by CADSS) that began shortly after dosing and typically resolved by 2 hours.[219]

The study titled Transform One submitted by the applicant is a Phase III, randomized, double-blind, active controlled, multi-center study which enrolled patients 18 years old to 64 years old who had been diagnosed with treatment-resistant depression for 28 days.[220] Patients were randomized (1:1:1) to receive SPRAVATO HCL 56 mg, 84 mg, or a placebo nasal spray administered twice weekly combined with a newly initiated, open-label oral anti-depressant (AD) administered daily (duloxetine, escitalopram, sertraline, or venlafaxine extended release), which was dosed according to a fixed titration schedule. Patients were assessed on the MADRS, CADSS, and discharge readiness as measured by overall clinical status and the Global Assessment of Discharge Readiness (CGADR). Discharge status was assessed at 1 and 1.5 hours. MADRS was assessed at 24 hours post initial dose and weekly thereafter. CADSS was assessed at baseline and all dosing visits.

Three hundred and fifteen patients of the 346 were randomized and completed the treatment phase; 115 patients were randomized to the 56 mg of SPRAVATO HCL dosage group along with 114 to the 84 mg of SPRAVATO HCL dosage group and 113 to the placebo group. The withdrawal rate was 3-fold higher in the 84 mg of SPRAVATO HCL dosage group (16.4 percent) than the 56 mg of SPRAVATO HCL dosage group (5.1 percent) and the placebo group (5.3 percent). Eleven of the 19 84 mg of SPRAVATO HCL dosage withdrawals withdrew after only receiving the first 56 mg SPRAVATO HCL dose; the withdrawal rate was not a dose-related safety finding. Baseline statistics show few differences between groups: The 56 mg of SPRAVATO HCL dosage group has a higher proportion of patients who have 1 or 2 previous AD medications (69 percent) as compared to the patients in the 84 mg of SPRAVATO HCL dosage group (51.8 percent) and placebo group (59.3 percent), and the placebo group (193.1) has a notably shorter duration of the current episode of depression in weeks as compared to the 56 mg of SPRAVATO HCL dosage group (202.8) and 84 mg of SPRAVATO HCL dosage group (212.7). The MADRS score was assessed by a mixed model for repeated measures with change from baseline as the response variable and the fixed effect model terms for treatment dosage, day, region, class of oral AD, a treatment-by-day moderating effect, and baseline value as a covariate.

The primary efficacy measure was assessed by change in MADRS score from baseline at 28 days. At the end of the study the 56 mg and 84 mg of SPRAVATO HCL dosage groups had a difference of least square means of −4.1 and −3.2, respectively. Neither of these were statistically significant differences as compared to the placebo. The least square mean treatment difference of MADRS score as compared to the placebo were also assessed longitudinally at baseline and the 2nd day (−3.0 for the 56 mg of SPRAVATO

[218] Daly, E., Singh, J., Fedgchin, M., Cooper, K., Lim, P., Shelton, R., Drevets, W., ''Efficacy and Safety of Intranasal Esketamine Adjunctive to Oral Anti-depressant Therapy in Treatment-Resistant Depression,'' *JAMA Psychiatry,* 2018, vol. 75(2), pp. 139–148.

[219] Daly, E., Singh, J., Fedgchin, M., Cooper, K., Lim, P., Shelton, R., Drevets, W., ''Efficacy and Safety of Intranasal Esketamine Adjunctive to Oral Anti-depressant Therapy in Treatment-Resistant Depression,'' *JAMA Psychiatry,* 2018, vol. 75(2), pp. 139–148.

[220] Fedgchin, M., Trivedi, M., Daly, E., Melkote, R., Lane, R., Lim, P., Singh, J., ''Randominzed, Double-blind Study of Fixed-dosed Intranasal Esketamine Plus Oral Anti-depressant vs. Active Control in Treatment-resistant Depression,'' 9th Biennial Conference of the International Society for Affective Disorders (ISAD) and the Houston Mood Disorders Conference, September 2018.

HCL dosage group and −2.2 for the 84 mg of SPRAVATO HCL dosage group), the 8th day (−3.0 for the 56 mg of SPRAVATO HCL dosage group and −2.7 for the 84 mg of SPRAVATO HCL dosage group), the 15th day (−3.8 for the 56 mg of SPRAVATO HCL dosage group and −3.6 for the 84 mg of SPRAVATO HCL dosage group), the 22nd day (−5.0 for the 56 mg of SPRAVATO HCL dosage group and −3.7 for the 84 mg of SPRAVATO HCL dosage group), and the 28th day (−4.0 for the 56 mg of SPRAVATO HCL dosage group and −3.6 for the 84 mg of SPRAVATO HCL dosage group). In a graph provided by the applicant, the lines plus standard errors plotted for the 56 mg and 84 mg of SPRAVATO HCL dosage groups overlap with each other at each time point, but do not appear to overlap with the placebo group (calculated confidence intervals would necessarily be wider and would possibly overlap).

A secondary efficacy measure was the rate of patients who are responders and remitters. Response is defined as greater than or equal to 50 percent improvement on MADRS from baseline. Remission is defined as a MADRS total score less than or equal to 12. The 56 mg and 84 mg of SPRAVATO HCL dosage treatment groups, 54.1 percent and 53.1 percent, respectively, had higher response rates than the placebo treatment group at 38.9 percent. The 56 mg and 84 mg of SPRAVATO HCL dosage treatment groups, 36.0 percent and 38.8 percent, had higher remission rates than the placebo treatment group at 30.6 percent.

Lastly, safety was assessed by adverse events and CADSS. Both the 56 mg and 84 mg of SPRAVATO HCL dosage treatment groups had spikes of CADSS scores, which spiked approximately 40 minutes post dose and resolved at 90 minutes. These post dose spikes gradually decreased from day 1 to day 25, but remained higher than the placebo group. The 84 mg of SPRAVATO HCL dosage treatment group had higher CADSS score spikes than the 56 mg of SPRAVATO HCL dosage treatment group at all periods except day 1. The top 5 of 12 pooled treatment group adverse events and percentages experienced are as follows: Nausea (29.4 percent), dissociation (26.8 percent), dizziness (25.1 percent), vertigo (20.8 percent), and headache (20.3 percent).

The study titled Transform Two is a Phase III, randomized (1:1), control trial, multi-center study enrolling patients 18 years old to 64 years old who had been diagnosed with treatment-resistant depression.[221] One hundred and fourteen patients were randomized to the treatment group and 109 to the control group; 101 and 100 of the treated and control groups respectively finished the study. For the treatment group, doses of SPRAVATO HCL began at 56 mg on the 1st day, with potential increases up to 84 mg until the 15th day at which point the dose remained stable. Two-thirds of the SPRAVATO HCL-treated patients were receiving the 84 mg dosage at the end of the study. For both the placebo and treatment groups, a newly-initiated AD was assigned by the investigator (duloxetine, escitalopram, sertraline, and venlafaxine extended release) following a fixed titration dosing.

The primary efficacy endpoint was the change from baseline at day 28 in MADRS total score, which was analyzed using a mixed-effects model using repeated measures (MMRM). The model included baseline MADRS total score as a covariate, and treatment, country, class of AD (SNRI or SSRI), day, and day-by-treatment moderator as fixed effects, and a random patient effect. The key secondary efficacy endpoints were as follows: The proportion of patients showing onset of clinical response by the 2nd day that was maintained for the duration of the treatment phase, the change from baseline in socio-occupational disability using the Sheehan Disability Scale (SDS) using the MMRM model, and the change from baseline in depressive symptoms using the patient health questionnaire 9-item (PHQ–9) using the MMRM model.

There were no apparent differences between the SPRAVATO HCL treatment and placebo groups at baseline. At day 28, the difference of least square means (standard error) for the SPRAVATO HCL-treated group was −4.0 (1.69) as compared to the placebo-treated group ($p<0.05$). Similar to Transform One, the difference of least square means for the SPRAVATO HCL-treated group as compared to the placebo-treated group were plotted for baseline and the 2nd, 8th, 15th, 22nd, and 28th day. At all treatment periods, except baseline and the 15th day, the SPRAVATO HCL treatment group had statistically significant lower scores than the placebo-treated group as indicated by 95 percent confidence intervals. The difference between the SPRAVATO HCL-treated and placebo-treated groups for the early onset of sustained clinical response was substantively similar and not statistically different. The difference of least square means (standard error) in socio-occupational disability as measured by SDS was −4.0 (1.17) for those in the SPRAVATO HCL-treated group as compared to the placebo-treated group ($p<0.05$). The difference of least square means (standard error) for the PHQ–9 total score for the SPRAVATO HCL-treated group compared to the placebo-treated group was −2.4 (0.88) ($p<0.05$). Lastly, 69.3 percent of the SPRAVATO HCL-treated patients as compared to 52.0 percent of the placebo-treated patients were considered responders and 52.5 percent of the SPRAVATO HCL-treated patients as compared to 31.0 percent of the placebo patients were considered remitters. The adverse events list, post dosing blood pressure increase, and post dosing CADSS spike were similar to those seen in the previous Transform One study.[222]

A post-hoc analysis based on Transform Two, which included 46 SPRAVATO HCL-treated and 44 placebo-treated patients was conducted to assess for differences in efficacy and safety between the U.S. population and the overall study population.[223] Efficacy was again assessed by MADRS, SDS, and PHQ–9 scores using the MMRM and with safety assessments for treatment-emergent adverse events (TEAEs), serious adverse events (SAEs), CADSS and other measures. At baseline the treated group of SPRAVATO HCL plus an AD was similar to the placebo-treated group who took only an AD on most measures to include average age, sex, race, class of oral ADs, MADRS, CGI–S, SDS, and PHQ–9 scores. The placebo-treated group had a longer average duration of current episode at 177.6 days as compared to 132.2 days for the SPRAVATO HCL-treated group; the placebo-treated group had a higher proportion of patients having 3 or more previous AD medications (50.1 percent) as compared to the SPRAVATO HCL treatment group (32.7 percent).

Both the SPRAVATO HCL-treated and placebo-treated groups showed

[221] Popova, V., Daly, E., Trivedi, M., Cooper, K., Lane, R., Lim, P., Singh, J., ''Randomized, Double-blind Study of Flexibly-dosed Intranasal Esketamine Pus Oral Anti-depressant vs. Active Control in Treatment-resistant Depression,'' Canadian College of Neuropsychopharmacology (CCNP) 41st Annual Meeting, 2018.

[222] Fedgchin, M., Trivedi, M., Daly, E., Melkote, R., Lane, R., Lim, P., Singh, J., ''Randominzed, Double-blind Study of Fixed-dosed Intranasal Esketamine Plus Oral Anti-depressant vs. Active Control in Treatment-resistant Depression,'' 9th Biennial Conference of the International Society for Affective Disorders (ISAD) and the Houston Mood Disorders Conference, September 2018.

[223] Alphs, L., Cooper, K., Starr, L., DiBernardo, A., Shawi, M., Jamieson, C., Singh, J., ''Clinical Efficacy and Safety of Flexibly Dosed Esketamine Nasal Spray in a US Population of Patients With Treatment-Resistant Depression,'' American Psychiatry Association, 2018, Chicago.

improvement on the efficacy measures after 28 days. At the endpoint of 28 days, the SPRAVATO HCL treatment group had a statistically significant MADRS total score least square mean difference of −5.5 ($p<0.05$) from the placebo treatment group. At the endpoint the median scores on the clinician-rated severity of depressive illness as measured by CGI–S were −1.5 and −1.0 for the SPRAVATO HCL-treated and placebo-treated groups respectively (one-sided p value >0.07). For the measure of patient-rated severity of depressive illness, the SPRAVATO HCL treatment group had a least square mean difference in PHQ–9 of −3.1 ($p<0.05$) as compared to the placebo treatment group. On the measure of functional impairment, the SPRAVATO HCL treatment group had a least square mean difference in SDS of −5.2 ($p<0.01$) as compared to the placebo treatment group. Overall treatment-emergent adverse events were observed in 91.3 percent of SPRAVATO HCL-treated patients and 77.3 percent of placebo-treated patients. One SPRAVATO HCL-treated patient experienced a serious adverse event of cerebral hemorrhage. Lastly, the top five most common adverse events were dizziness, nausea, headache, dysgeusia, and throat irritation.

The study titled Transform Three is a randomized (1:1), double-blind, active-controlled, multi-center study in elderly patients 65 years old and older who had been diagnosed with TRD.[224] Randomization was stratified by country and class of oral AD (SNRI and SSRI). All treatment patients started on a 28 mg dosage of SPRAVATO HCL and flexibly increased dosages of 56 mg or 84 mg based on investigator's determination of efficacy and tolerability. Both SPRAVATO HCL-treated (n=72) and placebo-treated (n=66) patients were started on a newly initiated AD (duloxetine, escitalopram, sertraline, and venlafaxine extended release). One hundred and twenty-two patients completed the double-blind phase, with 63 patients in the SPRAVATO HCL-treated group and 60 patients in the placebo-treated group.

The primary endpoint was the change in MADRS total score from the 1st day to the 28th day. Secondary endpoints included the evaluation of response and remission rates by group and the Clinical Global Impression—Severity (CGI–S) scores. The safety endpoints were evaluated by adverse event occurrence, laboratory tests, vital sign measurements, physical exams, and other exams.

At baseline, there were substantive differences between the placebo-treated and SPRAVATO HCL treatment groups in three measures. Patients from the SPRAVATO HCL treatment group (48.6 percent) were more likely to be from the European Union as compared to the placebo-treated group (36.9 percent). Patients from the SPRAVATO HCL treatment group were more likely to have 1 (20.8 percent versus 9.2 percent) to 4 (16.7 percent versus 6.2 percent) previous ADs as compared to the placebo-treated group. On the measure of duration of current episode of depression in weeks, the SPRAVATO HCL-treated group had an average (standard deviation) of 163.1 (277.04) as compared to the placebo-treated group with 274.1 (395.47). The primary endpoint, the change from baseline to Day 28 of MADRS score difference of least square means (95 percent CI) for the SPRAVATO HCL treatment group was −3.6 (−7.20,0.07) as compared to the placebo group. As with previous studies, the longitudinal change in MADRS total score is presented for baseline and at the 8th, 15th, 22nd, and 28th day. The results for the SPRAVATO HCL-treated group overlap with the placebo-treated group at each time point. At Day 28, 27.0 percent of the SPRAVATO HCL-treated patients as compared to 13.3 percent of the placebo-treated patients were considered responders and 17.5 percent of the SPRAVATO HCL-treated patients as compared to 6.7 percent of the placebo-treated patients were considered remitters. At baseline and the end of the study, 83.4 percent and 38.1 percent, respectively, of the SPRAVATO HCL-treated patients were rated as experiencing severe or marked symptoms on the CGI–S scale as compared to 66.1 percent and 54.4 percent, respectively, for those on the placebo.

Of the 72 patients who were treated with SPRAVATO HCL, 51 (70.8 percent) experienced a treatment-emergent adverse event (TEAE) as compared to 39 of the 65 (60.0 percent) placebo-treated patients. Five patients reported serious adverse events during the double-blind phase, three of whom were SPRAVATO HCL-treated patients and two of whom were placebo-treated patients. The top 5 of the 16 adverse events among the treated patients are dizziness (20.8 percent), nausea (18.1 percent), blood pressure increase (12.5 percent), fatigue (12.5 percent), and headache (12.5 percent).

A post-hoc analysis, which included 34 SPRAVATO HCL-treated patients and 36 placebo-treated patients from the Transform Three study, was performed to examine the response and remission associated with treatments in a subset of respondents 65 years old and older in the United States.[225] The MADRS, CGI–S, PHQ–9, and adverse event data were utilized to assess clinical outcomes. Remission was defined as a 50 percent or greater decrease in MADRS baseline score and remission was defined as a MADRS score of 12 or lower or a PHQ–9 score of less than 5. At baseline the SPRAVATO HCL-treated and placebo-treated groups were similar on the measures of age, sex, race, class of oral AD, age at major depressive disorder diagnosis, MADRS score, and CGI–S score. The SPRAVATO HCL treatment group differed from the placebo treatment group on the measures of mean duration of current depressive episode in weeks (187.6 versus 420.9) and mean PHQ–9 score (15.2 versus 18.2).

At the 28-day endpoint, response rates based on MADRS scores were 26.7 percent (n=30) for the SPRAVATO HCL-treated group and 14.7 percent (n=34) for the placebo-treated group. At the endpoint, remission rates based on MADRS scores were 16.7 percent (n=30) for the SPRAVATO HCL-treated group and 2.9 percent (n=34) for the placebo-treated group. Patient remission rates based on the PHQ–9 scores for SPRAVATO HCL-treated and placebo-treated patients were 9.4 percent (n=32) and 22.6 percent (n=31), respectively. Clinically meaningful response as measured by a one point or greater decrease in the CGI–S score was 63.3 percent (n=30) for the SPRAVATO HCL-treated group and 29.4 percent (n=34) for those on the placebo. Clinically significant response as measured by a decrease of two or greater on the CGI–S scale was 43.3 percent (n=30) for the SPRAVATO HCL-treated group and 11.8 percent (n=34) for those on the placebo. Lastly, 67.7 percent of the SPRAVATO HCL-treated patients and 58.3 percent of placebo-treated patients experienced a treatment-emergent adverse event. There was one serious adverse event in the SPRAVATO HCL-treated group (hip fracture) and placebo-treated group (dizziness) each. The top 5 most common adverse events in the 34

[224] Ochs-Ross, R., Daly, E., Lane, R., Zhang, Y., Lim, P., Foster, K., Sign, J., ''Efficacy and Safety of Esketamine Nasal Spray Plus an Oral Antidepressant in Elderly Patients with Treatment-resistant Depression,'' 2018 Annual Meeting of the American Psychiatric Association (APA), 2018, New York.

[225] Starr, L., Ochs-Ross, R., Zhang, Y., Singh, J., Lim, P., Lane, R., Alphs, L., ''Clinical Response, Remission, and Safety of Esketamine Nasal Spray in a US Population of Geriatric Patients With Treatment-Resistant Depression,'' American Psychiatric Association, 2018, New York.

SPRAVATO HCL-treated patients were dysphoria (11.8 percent), fatigue (11.8 percent), headache (11.8 percent), insomnia (11.8 percent), and nausea (11.8 percent).

The study titled Sustain One concerns a double-blind, randomized withdrawal, multi-center study entering either directly or after completing the double-blind phase of an acute, short-term study.[226] A total of 705 patients were enrolled in this study of which 437 entered directly into the study and the remainder transferred from one of two short-term SPRAVATO HCL studies (fixed dose, n=150; flexible dose, n=118). During the maintenance phase of this study, analyses were performed on two mutually exclusive groups: (1) On the stable remitters who were those randomized patients who were in stable remission at the end of the optimization phase and who received at least one dose of the study drug with one dose of an AD; and (2) on the stable responders who were those randomized patients who were stable responders at the end of optimization and who received at least one dose of the study drug with one dose of an AD. A relapse was defined as a MADRS total score of 22 or greater for 2 consecutive assessments separated by 5 to 15 days or hospitalization for worsening depression or any other clinically relevant event suggestive of relapse.

Of those classified in stable remission, 90 patients were receiving treatment with SPRAVATO HCL in combination with an AD and 86 patients were receiving treatment with the placebo in combination with an AD. Of those classified in stable response, 62 patients were receiving treatment with SPRAVATO HCL in combination with an AD and 59 patients were receiving treatment with the placebo in combination with an AD. At baseline, between group and within group randomization seems substantively successful, except for a lower proportion of placebo-treated stable responders being male (28.8 percent) as compared to SPRAVATO HCL-treated stable responders (38.7 percent), placebo-treated stable remitters (31.4 percent), and SPRAVATO HCL-treated stable remitters (35.6 percent).

Kaplan-Meier estimates of patients who remained relapse free were performed for both study groups. For both remitters and responders, the SPRAVATO HCL-treated had a higher percent of patients without relapse for longer than the control group. Overall, among the stable remitters, 24 (26.7 percent) of the patients in the SPRAVATO HCL-treated group and 39 (45.3 percent) of the patients in the placebo-treated group experienced a relapse event during the maintenance phase; among stable responders, 16 (25.8 percent) of the patients and 34 (57.6 percent) of the patients in the respective groups relapsed. Treatment with SPRAVATO HCL in combination with an AD decreased the risk of relapse by 51 percent (estimated hazard ratio = 0.49; 95 percent CI: 0.29, 0.84) among stable remitters and by 70 percent (hazard ratio = 0.30; 95 percent CI: 0.16, 0.55) among stable responders, as compared to the placebo.

Safety and adverse events were presented similarly to the previously discussed study data. The top 5 of the 22 adverse events were dysgeusia (27.0 percent), vertigo (25.0 percent), dissociation (22.4 percent), somnolence (21.1 percent), and dizziness (20.4 percent). The applicant stated that most adverse events were mild to moderate, observed post dose on dosing days, and generally resolved in the same day. Serious adverse events considered related to the study drug were reported for six patients in the SPRAVATO HCL treatment group (disorientation, hypothermia, lacunar stroke, sedation, and suicidal ideation for one patient each, and autonomic nervous system imbalance and simple partial seizure for one patient). The investigator considered the lacunar infarct as probably related to the treatment, while the sponsor considered the events of lacunar infarct and hypothermia as doubtfully related to the treatment. As with the previous studies, present-state dissociative symptoms and transient perceptual effects measured by the CADSS total score began shortly after the start of SPRAVATO HCL dosing, peaked at 40 minutes, and resolved by 1.5 hours.

The next study presented by the applicant titled Sustain Two concerns an open-label, long-term (up to 1 year of exposure), multi-center, single-arm, Phase III study for patients who had been diagnosed with TRD who entered into the study as either direct-entry or transferred-entry (patients who completed the double-blind, randomized, 4-week, Phase III, efficacy and safety study in elderly patients).[227] A total of 802 patients were enrolled; 779 entered in the induction phase (691 as direct-entry and 88 as transferred-entry non-responders). A total of 603 patients entered the optimization/maintenance phase (580 from the induction phase and 23 were transferred-entry responders). A total of 150 (24.9 percent) of the patients completed the optimization/maintenance phase. At that time, the predefined total patient exposure was met and the study was stopped by the sponsor; 331 (54.9 percent) of the patients were still receiving treatment and, therefore, discontinued the study. Patients treated had a starting dose of 56 mg of SPRAVATO HCL, or 28 mg for patients who were 65 years old or older, followed by flexible dosing increases (28 mg to 84 mg per clinical judgment) twice a week for 4 weeks. Dosages became stable at 15 days for those under 65 years old, and at 18 days for those 65 years old and older.

At baseline, 802 respondents had an average age of 52.2 years old, 62.6 percent were women, 85.5 percent were white, an average BMI of 27.9 percent, and 43.1 percent with a family history of depression. The anti-depressants prescribed to these respondents were duloxetine (31.1 percent), escitalopram (29.6 percent), sertraline (19.6 percent), and venlafaxine extended release (19.5 percent). Of the respondents at baseline, 39.9 percent had used 3 or more ADs prior to the study with no response. Safety measures were reported at 4 weeks, 48 weeks, and pooled. For TEAEs, 83.8 percent of patients experienced at least one at 4 weeks and 85.6 percent at 48 weeks. TEAEs occurred in 90.1 percent (n=723) of all patients and led to discontinuation in 9.5 percent of both the pooled 4 and 48 week patient samples. TEAEs caused 2 deaths (acute respiratory and cardiac failure, and completed suicide; neither death considered as related by investigator) at 48 weeks. The top 5 most common TEAEs for the 4-week and 48-week time points were dizziness (29.3 percent and 22.4 percent), dissociation (23.1 percent and 18.6 percent), nausea (20.2 percent and 13.9 percent), headache (17.6 percent and 18.9 percent), and somnolence (12.1 percent and 14.1 percent). At 4 weeks, 2.2 percent of the patients experienced at least 1 serious adverse event and 6.3 percent at 48 weeks. Of the 68 serious adverse events, 63 were assessed as not related or doubtfully related to

[226] Daly, E., Trivedi, M., Janik, A., Li, H., Zhang, Y., Li, X., Singh, J., ''A Randomized Withdrawal, Double-blind, Multicenter Study of Esketamine Nasal Spray Plus an Oral Anti-depressant for Relapse Prevent in Treatment-resistant Depression,'' 2018 Annual Meeting of the American Society of Clinical Psychopharmacology (ASCP), 2018, Miami.

[227] Wajs, E., Aluisio, L., Morrison, R., Daly, E., Lane, R., Lim, P., Singh, J., ''Long-term Safety of Esketamine Nasal Spray Plus Oral Anti-depressant in Patients with Treatment-resistant Depression: Phase III, Open-label, Safety and Efficacy Study (SUSTAIN–2),'' 2018 Annual Meeting of the American Society of Clinical Psychopharmacology (ASCP), 2018, Miami.

treatment involving SPRAVATO HCL by the investigator. Five of the serious adverse events (anxiety, delusion, delirium, suicidal ideation and suicide attempt) were considered as treatment related. Overall, performance on multiple cognitive domains including visual learning and memory, as well as spatial memory/executive function either improved or remained stable post baseline in both elderly and younger patients.

Based on all of the above, the applicant concluded that the use of SPRAVATO HCL represents a substantial clinical improvement over existing technologies. CMS has the following concerns regarding whether SPRAVATO HCL meets the substantial clinical improvement criterion.

First, we are concerned that the use of the placebo in combination with a newly prescribed anti-depressant may not be the most appropriate comparator when assessing the clinical improvement of the use of SPRAVATO HCL as compared to existing therapies. In its application, the applicant listed multiple treatment options aside from the use of anti-depressants, which are currently available to treat diagnoses of TRD. It is possible that other treatments approved for diagnoses of TRD may obtain better treatment outcomes than changing to a new single anti-depressant (as was the method used in the studies submitted in support of this application). Comparisons with existing treatments for treatment-resistant major depressive disorders would help us better evaluate the clinical improvements offered by the use of SPRAVATO HCL.

Second, we are not certain that the results in the studies submitted consistently show that the use of SPRAVATO HCL represents a substantial clinical improvement when compared to existing therapies. There does not appear to be a consistent statistically significant positive primary efficacy outcome for SPRAVATO HCL-treated patients compared to placebo-treated patients. Based on the data provided, we also are uncertain of the extent to which the findings from the submitted studies apply to the broader Medicare population. We are particularly concerned that there are few substantive and statistically significant improvements in depression outcomes with SPRAVATO HCL treatment among the Medicare-aged participants of the study samples. In addition, the studies which limit their analyses to Medicare-aged study participants have limited racial diversity amongst small samples. In addition, we note that the submitted studies excluded patients with significant medical and psychiatric comorbidities through exclusion criteria. However, the likelihood of having multiple chronic comorbid conditions is increased amongst those with a mental health disorder [228] [229] and for the elderly.[230] [231] The existence of comorbidities increases the likelihood that the negative effects of poly-pharmacy and drug-drug interactions could be experienced among the Medicare population. Given that the provided studies utilized exclusion criteria, which excluded those with serious comorbidities, we are concerned that the limited results do not adequately represent the average or even the majority of the Medicare population.

Third, we have concerns regarding the primary and secondary endpoints for several of these studies. It is unclear whether the primary endpoint of these studies (change in baseline MADRS) is the most appropriate endpoint to assess substantial clinical improvement, particularly as it unclear what threshold degree of change was defined as meeting the definition of change from baseline in the analyses, and whether this degree of change translates to clinical improvement (for example, response and remissions rates). In addition, we have concerns regarding the potential for physician behavior to have introduced bias, which could impact the study results. The studies state that anti-depressants are physician assigned and not randomized. Some of the provided studies control for the type of anti-depressant prescribed (SSRI and SNRI). We believe there is the potential for an interaction effect between the prescribed anti-depressant and SPRAVATO HCL. It is possible that one particular anti-depressant (of the anti-depressants used in the studies)/SPRAVATO HCL combination accounts for the entirety of the differences seen between the treated groups and the control groups. Without consistently controlling for the specific anti-depressants prescribed in multivariate analyses, we may not be able to parse this potentially complex relation apart.

Fourth, given that SPRAVATO HCL is comprised of the drug ketamine, we are concerned with the potential for abuse. Ketamine is accepted as a medication for which there is a strong possibility for abuse.[232] [233] [234] As one publication finds, current abuse of intravenous ketamine occurs intranasally.[235] While clinical trials assess the short-term benefits of ketamine treatment, there exists a paucity of long-term studies to assess whether chronic usage of this product may increase the likelihood of abuse.[236] In light of the potential for addictive behavior, we are concerned that despite any demonstrated short-term clinical benefits, there may be potential negatives for the use of this drug in the longer term.

We are inviting public comments on whether SPRAVATO HCL meets the substantial clinical improvement criterion. We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for SPRAVATO HCL or at the New Technology Town Hall meeting.

k. XOSPATA

Astellas Pharma U.S., Inc. submitted an application for new technology add-on payments for XOSPATA® (gilteritinib) for FY 2020. XOSPATA® received FDA approval November 28, 2018, and is indicated for the treatment of adult patients who have been diagnosed with relapsed or refractory acute myeloid leukemia (AML) with a

[228] Thorpe, K., Jain, S., & Joski, P., ''Prevalence and Spending Associated with Patients Who have a Behavioral Health Disorder and Other Conditions,'' *Health Affairs,* 2017, vol. 36(1), pp. 124–132, doi:10.1377/hlthaff.2016.0875.

[229] Druss, B., & Walker, E., 2011, ''Mental Disorders and Medical Comorbidity,'' Robert Wood Johnson Foundation, 2011. Available at: *http://www.policysynthesis.org.*

[230] Kim, J., & Parish, A., ''Polypharmcy and Medication Management in Older Adults,'' *Nurs Clin N Am,* 2017, vol. 52, pp. 457–468, doi:*http://dx.doi.org/10.1016/j.cnur.2017.04.007.*

[231] Kim, L., Koncilja, K., & Nielsen, C., ''Medication Management in Older Adults,'' *Cleveland Clinic Journal of Medicine,* 2018, vol. 85(2), pp. 129–135, doi:10.3949/ccjm.85a.16109.

[232] Schak, K., Vande Voort, J., Johnson, E., Kung, S., Leung, J., Rasmussen, K., Frye, M., ''Potential Risks of Poorly Monitored Ketamine Use in Depression Treatment,'' *American Journal of Psychiatry,* 2016, vol. 173(3), pp. 215–218. Available at: *http://www.ajp.psychiatryonline.org.*

[233] Freedman, R., Brown, A., Cannon, T., Druss, B., Earls, F., Escobar, J., Xin, Y., ''Can a Framework be Established for the Safe Use of Ketamine?,'' *American Journal of Psychiatry,* 2018, vol. 7, pp. 587–589. Available at: *http://www.ajp.psychiatryonline.org.*

[234] Sanacora, G., Frye, M., McDonald, W., Mathew, S., Turner, M., Schatzberg, A., Nemeroff, C., ''A Consensus Statement on the Use of Ketamine in the Treatment of Mood Disorders,'' *JAMA Psychiatry,* 2017, Special Communication, E1–E6. doi:10.1001/jamapsychiatry.2017.0080.

[235] Schak, K., Vande Voort, J., Johnson, E., Kung, S., Leung, J., Rasmussen, K., Frye, M., ''Potential Risks of Poorly Monitored Ketamine Use in Depression Treatment,'' *American Journal of Psychiatry,* 2016, vol. 173(3), pp. 215–218. Available at: *http://www.ajp.psychiatryonline.org.*

[236] Sanacora, G., Frye, M., McDonald, W., Mathew, S., Turner, M., Schatzberg, A., Nemeroff, C., ''A Consensus Statement on the Use of Ketamine in the Treatment of Mood Disorders,'' *JAMA Psychiatry,* 2017, Special Communication, E1–E6. doi:10.1001/jamapsychiatry.2017.0080.

FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

According to the applicant, XOSPATA® is an oral, small molecule FMS-like tyrosine kinase 3 (FLT3). The applicant states that XOSPATA® inhibits FLT3 receptor signaling and proliferation in cells exogenously expressing FLT3, including FLT3 internal tandem duplication (ITD), tyrosine kinase domain mutations (TKD) FLT3D835Y and FLT3–ITD–D835Y and that it induces apoptosis in leukemic cells expressing FLT3–ITD. FLT3 is a member of the class III receptor tyrosine kinase family that is normally expressed on the surface of hematopoietic progenitor cells, but it is over expressed in the majority of AML cases.

The applicant states that AML is a type of cancer in which the bone marrow makes abnormal myeloblasts (a type of white blood cell), red blood cells, or platelets. According to the applicant, AML is a rare and rapidly progressing form of cancer of the blood and bone marrow, characterized by the proliferation of immature white blood cells known as blast cells. The applicant states that while the specific cause of AML is unknown, AML is generally characterized by aberrant differentiation and increased proliferation of malignantly transformed myeloid progenitor cells. It is considered a heterogeneous disease state with various molecular and genetic abnormalities, which result in variable clinical outcomes. When untreated or refractory to available treatments, AML results in the accumulation of these transformed cells within the bone marrow and suppression of the production of normal blood cells (resulting in severe neutropenia and/or thrombocytopenia). AML may be associated with infiltration of these cells into other organs and tissues and can be rapidly fatal.

Almost 90 percent of leukemia cases are diagnosed in adults 20 years of age and older, among whom the most common types are chronic lymphocytic leukemia and AML.[237] AML accounts for approximately 80 percent of acute leukemias diagnosed in adults, with a median age at diagnosis of 66 years old. It has been estimated that 19,520 people are diagnosed annually with AML in the United States.[238] In general, the incidence of AML increases with advancing age; the prognosis is poorer in older patients, and the tolerability of the currently available standard-of-care treatment for patients who have been diagnosed with AML is much poorer for older patients.[239]

According to the applicant, approximately 30 percent of adult patients who have been diagnosed with AML are refractory, meaning unresponsive, to induction therapy. Furthermore, of those who achieve complete response (CR), approximately 75 percent will relapse. These patients are then determined to have relapsed/refractory (R/R) AML. According to the applicant, several chemotherapy regimens have been used for the treatment of patients who have been diagnosed with resistant or relapsed disease; however, the chemotherapy combinations are universally dose-intensive and cannot always be easily administered to older patients because of a high-risk of unacceptable toxicity. The applicant indicated that, while these regimens may generate second remission rates of up to 50 percent in patients with a first remission of more than 1 year, toxicity is high in most patients who are frail or over 60 years old.[240] [241] [242] Additionally, the applicant stated that if patients (including younger patients) relapse within 6 months of their initial CR, the chance of attaining a second remission is less than 20 percent with chemotherapy alone.[243] Furthermore, 5-year survival after first relapse is approximately 10 percent, demonstrating the lack of an effective cure for patients who have been diagnosed with relapsed AML.[244] Salvage therapy utilizing low-dose chemotherapy provides a therapy that is more tolerable; however, the low response rates (17 to 21 percent) makes the benefit of these agents limited.[245] [246] Patients who are in second relapse or are refractory to first salvage, meaning unresponsive to both the preferred treatment, as well as the secondary choice of treatment, have an extremely poor prognosis, with survival measured in weeks.[247] Additionally, patients who have been diagnosed with R/R AML have poor quality of life, higher hospitalization and total resource use burden, and higher total healthcare costs.[248] [249] [250] [251]

The applicant indicated that patients who have been diagnosed with AML with FLT3 positive mutations are a well-established subpopulation of AML patients, but there are no approved therapies for patients who have been diagnosed with R/R AML with FLT3 mutations. Approximately 30 percent of patients newly diagnosed with AML have mutations in the FLT3 gene.[252] [253] FLT3 is a member of the class III receptor tyrosine kinase family that is normally expressed on the surface of hematopoietic progenitor cells. FLT3 and its ligand play an important role in proliferation, survival, and differentiation of multipotent stem cells. The applicant explained that FLT3 is overexpressed in the majority of patients diagnosed with AML. In addition, activated FLT3 with internal tandem duplication (ITD) or tyrosine kinase domain (TKD) mutations at around D835 in the activation loop are present in 20 percent to 25 percent and

[237] Atlanta: American Cancer Society; 2017 [cited October 2018]. Available from: *https://www.cancer.org/content/dam/cancerorg/research/cancer-facts-and-statistics/cancer-treatment-and-survivorship-facts-and-figures/cancer-treatment-and-survivorshipfacts-and-figures-2016-2017.pdf.*

[238] Siegel, R.L., Miller, K.D., Jemal, A., ''Cancer statistics, 2018,'' *CA Cancer J Clin,* 2018, vol. 68(1), pp. 7–30.

[239] Tallman, M.S., ''New strategies for the treatment of acute myeloid leukemia including antibodies and other novel agents,'' Hematology Am Soc Hematol Educ Program, 2005, pp. 143–50.

[240] Rowe, J.M., Tallman, M.S., ''How I treat acute myeloid leukemia,'' *Blood,* 2010, vol. 116(17), pp. 3147–56.

[241] Breems, D.A., Van Putten, W.L., Huijgens, P.C., Ossenkoppele, G.J., Verhoef, G.E., Verdonck, L.F., et al., ''Prognostic index for adult patients with acute myeloid leukemia in first relapse,'' *J Clin Oncol,* 2005, vol. 23(9), pp. 1969–78.

[242] Karanes, C., Kopecky, K.J., Head, D.R., Grever, M.R., Hynes, H.E., Kraut, E.H., et al., ''A Phase III comparison of high dose ARA–C (HIDAC) versus HIDAC plus mitoxantrone in the treatment of first relapsed of refractory acute myeloid leukemia Southwest Oncology Group Study,'' *Leuk Res,* 1999, vol. 23(9), pp. 787–94.

[243] Forman, S.J., Rowe, J.M., ''The myth of the second remission of acute leukemia in the adult,'' *Blood,* 2013, vol. 121(7), pp. 1077–82.

[244] Rowe, J.M., Tallman, M.S., ''How I treat acute myeloid leukemia,'' *Blood,* 2010, vol. 116(17), pp. 3147–56.

[245] Itzykson, R., Thepot, S., Berthon, C., et al., ''Azacitidine for the treatment of relapsed and refractory AML in older patients,'' *Leuk Res,* 2015, vol. 39, pp. 124–130.

[246] Khan, N., Hantel, A., Knoebel, R., et al., ''Efficacy of single-agent decitabine in relapsed and refractory acute myeloid leukemia,'' *Leuk Lymphoma,* 2017, vol. 58, pp. 1–7.

[247] Giles, F., O'Brien, S., Cortes, J., Verstovsek, S., Bueso-Ramos, C., Shan, J., et al., ''Outcome of patients with acute myelogenous leukemia after second salvage therapy,'' *Cancer,* 2005, vol. 104(3), pp. 547–54.

[248] Goldstone, A.H., et al., ''Attempts to improve treatment outcomes in acute myeloid leukemia (AML) in older patients: the results of the United Kingdom Medical Research Council AML11 trial,'' *Blood,* 2001, vol. 98(5), pp. 1302–1311.

[249] Pandya, B.J., et al., ''Quality of life of Acute Myeloid Leukemia Patients in a Real-World Setting,'' *JCO,* 2017, vol. 35(15) suppl., e18525.

[250] Medeiros, B.C., et al., ''Economic Burden of Treatment Episodes in Acute Myeloid Leukemia (AML) Patients in the US: A Retrospective Analysis of a Commercial Payer Database,'' ASH, 2017 Poster.

[251] Aly, A., et al., ''Economic Burden of Relapsed/Refractory AML in the U.S.,'' ASH, 2017 Poster.

[252] The Cancer Genome Atlas Research Network, ''Genomic and Epigenomic Landscapes of Adult De Novo Acute Myeloid Leukemia,'' *N Engl J Med,* 2013, vol. 368(22), pp. 2059–2074.

[253] Leukemia and Lymphoma Society Facts 2016–2017. Available at: *https://www.lls.org/facts-and-statistics/facts-and-statistics-overview,* [Last accessed March 7, 2018].

5 percent to 10 percent of AML cases, respectively.[254] These activated mutations in FLT3 are oncogenic and show transforming activity in cells.[255]

Compared to patients with wild-type FLT3, AML patients with FLT3 mutation experience shorter remission duration at 2 years, according to the applicant. Approximately 30 percent of FLT3–ITD patients relapse versus approximately 16 percent of other AML patients.[256] Additionally, these patients experience poorer survival outcomes. The estimated median OS for patients who have been newly diagnosed with FLT3 mutations is 15.2 to 15.5 months compared to 19.3 to 28.6 months for patients with wild-type FLT3.[257] Patients who have been diagnosed with R/R FLT3 mutation positive AML have lower remission rates with salvage chemotherapy, shorter durations of remission to second relapse and decreased overall survival relative to FLT3 mutation negative patients.[258] [259] [260] According to the applicant, patients who have been diagnosed with FLT3 mutation positive R/R AML have a substantial unmet medical need for treatment.

The applicant asserts that currently there are no unique ICD–10–PCS codes to describe the administration of XOSPATA®. We note that the applicant has submitted a request to the ICD–10 Coordination and Maintenance Committee for approval for a unique ICD–10–PCS code to identify procedures involving the use of XOSPATA®, beginning in FY 2020.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that XOSPATA® has a unique mechanism of action and, therefore, should be considered new under this criterion. The applicant stated that XOSPATA® is an oral, small molecule FMS-like tyrosine kinase 3 (FLT3) inhibitor. According to the applicant, XOSPATA® inhibits FLT3 receptor signaling and proliferation in cells exogenously expressing FLT3, including FLT3 internal tandem duplication (ITD), tyrosine kinase domain mutations (TKD) FLT3–D835Y and FLT3–ITD D835Y, and it induces apoptosis in leukemic cells expressing FLT3–ITD. The applicant asserted that XOSPATA® is the only FLT3-targeting agent approved by the FDA for the treatment of relapsed or refractory FLT3mut+ AML.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant asserted that cases involving patients being medically treated for the type of AML indicated for XOSPATA® would map to the following MS–DRGs: 834 (Acute Leukemia without Major O.R. Procedure with MCC), 835 (Acute Leukemia without Major O.R. Procedure with CC), and 836 (Acute Leukemia without Major O.R. Procedure without CC/MCC). Under current coding conventions, it appears likely that cases involving treatment with the use of XOSPATA® would map to the same MS–DRGs as existing therapies.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that XOSPATA® is FDA-approved for the treatment of adult patients who have relapsed or refractory AML with a FLT3 mutation. Cases representing potential patients that may be eligible for treatment involving XOSPATA® would be identified by ICD–10–CM diagnostic codes C92.02 (Acute myeloblastic leukemia, in relapse) and C92.A2 (Acute myeloid leukemia with multilineage dysplasia, in relapse). The applicant further asserted that there are currently no other FLT3-targeting agents approved for the treatment of patients who have been diagnosed with relapsed or refractory FLT3mut+ AML. Therefore, the applicant asserted that XOSPATA® is indicated to treat a new patient population for which there are no other technologies currently available.

We are inviting public comments on whether XOSPATA® is substantially similar to any existing technologies, and whether it meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion.

The applicant searched the FY 2017 MedPAR data file for cases reporting ICD–10–CM diagnosis codes C92.02 (Acute myeloblastic leukemia, in relapse) and C92.A2 (Acute myeloid leukemia with multilineage dysplasia, in relapse) listed as a primary or secondary diagnosis that mapped to MS–DRGs 834, 835, and 836. The applicant applied the following trims to the cases:

- Excluded Health Maintenance Organization (HMO) and IME Only claims;
- Excluded cases for bone marrow transplant because potential eligible patients who may receive treatment involving XOSPATA® would not receive a bone marrow transplant during the same admission as they received chemotherapy;
- Excluded cases indicating an O.R. procedure;
- Excluded cases treated at 8 providers that were not listed in the FY 2019 IPPS/LTCH PPS final rule correction notice impact file (these are predominately cancer hospitals).

After applying the trims above, 407 potential cases remained. The applicant noted that it used only departmental charges that are used by CMS for ratesetting.

Using the 407 cases, the applicant determined an average case-weighted unstandardized charge per case of $166,389. The applicant then removed all pharmacy charges because the applicant believed that patients would typically receive other pharmaceuticals such as anti-emetics during the hospital stay and patients receiving treatment involving the use of XOSPATA® would continue to receive those receive other pharmaceuticals. Additionally, according to the applicant, blood charges were reduced because some patients receiving treatment involving the use of XOSPATA® became infusion independent in the clinical trial. The applicant standardized the charges for each case and inflated each case's charges by applying the proposed outlier charge inflation factor of 1.085868 (included in the FY 2019

[254] Kindler, T., Lipka, D.B., Fischer, T., ''FLT3 as a therapeutic target in AML: still challenging after all these years,'' *Blood,* 2010, vol. 116(24), pp. 5089–102.

[255] Yamamoto, Y., Kiyoi, H., Nakano, Y., Suzuki, R., Kodera, Y., Miyawaki, S., et al., ''Activating mutation of D835 within the activation loop of FLT3 in human hematologic malignancies,'' *Blood,.* 2001, vol. 97, pp. 2434–9.En

[256] Brunet, S., et al., ''Impact of FLT3 Internal Tandem Duplication on the Outcome of Related and Unrelated Hematopoietic Transplantation for Adult Acute Myeloid Leukemia in First Remission: A Retrospective Analysis,'' *J Clin Oncol,* March 1, 2012, vol. 30(7), pp. 735–41.

[257] Sotak, M.L., et al., ''Burden of Illness of FLT3 Mutated Acute Myeloid Leukemia (AML),'' *Blood,* 2011, vol. 118(21), pp. 4765 4765.

[258] Konig, H., Levis, M., ''Targeting FLT3 to treat leukemia. Expert Opin Ther Targets,'' 2015, vol. 19(1), pp. 37–54.

[259] Chevallier, P., Labopin, M., Turlure, P., Prebet, T., Pigneux, A., Hunault, M., et al., ''A new Leukemia Prognostic Scoring System for refractory/relapsed adult acute myelogeneous leukaemia patients: a GOELAMS study,'' *Leukemia,* 2011, vol. 25(6), pp. 939–44.

[260] Levis, M., Ravandi, F., Wang, E.S., Baer, M.R., Perl, A., Coutre, S., et al., ''Results from a randomized trial of salvage chemotherapy followed by lestaurtinib for patients with FLT3 mutant AML in first relapse,'' *Blood,* 2011, vol. 117(12), pp. 3294–301.

IPPS/LTCH PPS proposed rule (83 FR 20581)). The applicant calculated an average case-weighted standardized charge per case of $157,034 using the percent distribution of MS–DRGs as case-weights. Based on this analysis, the applicant determined that the technology met the cost criterion because the final inflated average case-weighted standardized charge per case for XOSPATA® exceeded the average case-weighted threshold amount of $88,479 by $68,555. As noted, the inflation factor used by the applicant was the proposed 2-year inflation factor, which was discussed in the FY 2019 IPPS/LTCH PPS final rule summation of the calculation of the FY 2019 IPPS outlier charge inflation factor for the proposed rule (83 FR 41718 through 41722). The final 2-year inflation factor published in the FY 2019 IPPS/LTCH PPS final rule was 1.08864 (83 FR 41722), which was revised in the FY 2019 IPPS/LTCH PPS final rule correction notice to 1.08986 (83 FR 49844).

We note that, although the applicant used the proposed rule value to inflate the standardized charges, even when using the final rule value or the corrected final rule value revised in the correction notice to inflate the charges, the final inflated average case-weighted standardized charge per case for XOSPATA® would exceed the average case-weighted threshold amount. We are inviting public comments on whether XOSPATA® meets the cost criterion.

With regard to substantial clinical improvement, the applicant submitted one central study to support its assertion that XOSPATA® represents a substantial clinical improvement over existing technologies because it offers a treatment option for FLT3mut+ AML patients ineligible for currently available treatments. The applicant also asserted that XOSPATA® represents a substantial clinical improvement because the technology reduces mortality, decreases the number of subsequent diagnostic or therapeutic interventions, and reduces the number of future hospitalizations due to adverse events as shown by its studies.[261]

According to the applicant, the efficacy of XOSPATA® in the treatment of patients who have been diagnosed with R/R AML has been demonstrated in a U.S.-based, multi-national, active-controlled, Phase III study (ADMIRAL, 2215–CL–0301). This study was designed to determine the clinical benefit of the use of XOSPATA® in patients who have been diagnosed with FMS-like tyrosine kinase (FLT3) mutated AML who are refractory to, or have relapsed, after first-line AML therapy as shown with overall survival (OS) compared to salvage chemotherapy, and to determine the efficacy of the use of XOSPATA® as assessed by the rate of complete remission and complete remission with partial hematological recovery (CR/CRh) in these patients.[262]

In the ADMIRAL (2215–CL–0301) study, the applicant noted that XOSPATA® demonstrated clinically meaningful CR and CRh rates, as well as a clinically meaningful duration of CR/CRh in the patients studied. The CR/CRh rate was 21.8 percent, with 31/142 patients achieving a CR/CRh, 18/142 patients achieving CR (12.7 percent) and 13/142 patients achieving a CRh (9.2 percent). Of the 31 patients (21.8 percent) who achieved CR/CRh, the median duration of remission was 4.5 months. For the 18 patients who achieved CR and the 13 patients who achieved CRh, the median duration of response was 8.7 months and 2.9 months, respectively.[263]

The safety evaluation of XOSPATA® is based on 292 patients who had been diagnosed with relapsed or refractory AML treated with 120 mg of XOSPATA® daily. The applicant noted that when looking at the ADMIRAL study, the most common serious adverse events (SAEs) (Grade III or above) were lab abnormalities of elevation of liver transaminases in 43 (15 percent) of patients, fatigue in 14 (5 percent) of patients, myalgia or arthralgia in 13 (5 percent) of patients, and gastrointestinal disorders of diarrhea in 8 (3 percent) of patients and nausea in 4 (1 percent) of patients. Due to the number and type of SAEs reported, the applicant believed that XOSPATA® has the potential to decrease the number of subsequent future hospitalizations or physician visits as a result of management of adverse events, in particular serious adverse events.

Transfusion dependence was also evaluated in the XOSPATA®-treated patients. In some hematologic disorders, becoming transfusion independent or receiving fewer transfusions over a specified interval is defined as improvement or response depending on whether therapy is given.[264]

In the ADMIRAL study, at baseline prior to therapy initiation, 34 patients in the XOSPATA® arm were classified as transfusion independent and 107 patients were classified as transfusion dependent. Of these transfusion dependent patients, 34 (31.8 percent) patients became transfusion independent during XOSPATA® treatment. Of the 34 patients who were transfusion independent at baseline, 18 (52.9 percent) patients maintained transfusion independence during XOSPATA® treatment.

The applicant asserted that the use of XOSPATA® addresses a medical need in a patient population that has been difficult to manage in the past due to limited treatment options. In the ADMIRAL study, the applicant provided data specific to reduced mortality rate compared to historical data. Because of the small number of SAEs, the applicant stated that it anticipates reduction of subsequent diagnostic and therapeutic interventions, as well as decreased number of future physician visits and hospitalization as noted previously. However, the applicant did not provide direct numbers for the comparator arm of the ADMIRAL study in its application. Because of this, we are concerned that it may be difficult to determine XOSPATA®'s comparative effectiveness. We note that, the ADMIRAL study was designed to evaluate efficacy and head-to-head trials are lacking. Until the comparative data for both randomized arms are available, we are concerned that there may be insufficient evidence to determine that XOSPATA® provides a substantial clinical improvement over existing technologies.

We are inviting public comments on whether XOSPATA® meets the substantial clinical improvement criterion. We did not receive any written public comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for XOSPATA® or at the New Technology Town Hall meeting.

l. GammaTile™

GT Medical Technologies, Inc. submitted an application for new technology add-on payments for FY 2020 for the GammaTile™. We note that Isoray Medical, Inc. and GammaTile, LLC previously submitted an application for new technology add-on payments for GammaTile™ for FY

[261] Astellas, ''A Phase 3 Open-label, Multicenter, Randomized Study of ASP2215 versus Salvage Chemotherapy in Patients with Relapsed or Refractory Acute Myeloid Leukemia (AML) with FLT3 Mutation, Clinical Study Report,'' March 2018.

[262] Ibid.

[263] Draft XOSPATA® (package insert) Northbrook, IL, Astellas Pharma US, Inc., 2018.

[264] Gale, R.P., Barosi, G., Barbui, T., Cervantes, F., Dohner, K., Dupriez, B., et al., ''What are RBC-transfusion-dependence and -independence?,'' *Leuk. Res,* 2011, vol. 35(1).

2018, which was withdrawn, and also for FY 2019, however the technology did not receive FDA approval or clearance by July 1, 2018 and, therefore, was not eligible for consideration for new technology add-on payments. The GammaTile™ is a brachytherapy technology for use in the treatment of patients who have been diagnosed with brain tumors, which uses cesium-131 radioactive sources embedded in a collagen matrix. GammaTile™ is designed to provide adjuvant radiation therapy to eliminate remaining tumor cells in patients who required surgical resection of brain tumors. According to the applicant, the GammaTile™ technology is a new vehicle of delivery for and inclusive of cesium-131 brachytherapy sources embedded within the product. The applicant stated that the technology has been manufactured for use in the setting of a craniotomy resection site where there is a high chance of local recurrence of a CNS or dual-based tumor. The applicant asserted that the use of the GammaTile™ technology provides a new, unique modality for treating patients who require radiation therapy to augment surgical resection of malignancies of the brain. By offsetting the radiation sources with a 3mm gap of a collagen matrix, the applicant asserted that the use of the GammaTile™ technology resolves issues with ''hot'' and ''cold'' spots associated with brachytherapy, improves safety, and potentially offers a treatment option for patients with limited, or no other, available options. The GammaTile™ is biocompatible and bioabsorbable, and is left in the body permanently without need for future surgical removal. The applicant asserted that the commercial manufacturing of the product will significantly improve on the process of constructing customized implants with greater speed, efficiency, and accuracy than is currently available, and requires less surgical expertise in placement of the radioactive sources, allowing a greater number of surgeons to utilize brachytherapy techniques in a wider variety of hospital settings.

The GammaTile™ technology received FDA clearance under section 510(k) as a Class II medical device on July 6, 2018. The FDA application included the indication for GammaTile™ to be used to provide radiation therapy for patients who have been diagnosed with recurrent intercranial neoplasms. The applicant submitted a request for approval for a unique ICD–10–PCS code for the use of the GammaTile™ technology, which was approved effective October 1, 2017 (FY 2018). The ICD–10–PCS procedure code used to identify procedures involving the use of the GammaTile™ technology is 00H004Z (Insertion of radioactive element, cesium-131 collagen implant into brain, open approach).

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated that when compared to treatment using external beam radiation therapy, GammaTile™ uses a new and unique mechanism of action to achieve a therapeutic outcome. The applicant explained that the GammaTile™ technology is fundamentally different in structure, function, and safety from all external beam radiation therapies, and delivers treatment through a different mechanism of action. In contrast to external beam radiation modalities, the applicant further explained that the GammaTile™ is a form of internal radiation termed brachytherapy. According to the applicant, brachytherapy treatments are performed using radiation sources positioned very close to the area requiring radiation treatment and deliver radiation to the tissues that are immediately adjacent to the margin of the surgical resection. Conversely, external beam radiation therapy travels inward and typically exposes radiation to a large volume of normal brain tissue. As a result, the common clinical practice to avoid radiation toxicity is to reduce dosage ranges, limiting overall efficacy.

Due to the custom positioning of the radiological sources and the use of the cesium-131 isotope, the applicant noted that the GammaTile™ technology focuses therapeutic levels of radiation on an extremely small area of the brain. Unlike all external beam techniques, the applicant stated that this radiation does not pass externally inward through the skull and healthy areas of the brain to reach the targeted tissue and, therefore, may limit neurocognitive deficits seen with the use of external beam techniques. Because of the rapid reduction in radiation intensity that is characteristic of cesium-131, the applicant asserted that the GammaTile™ technology can target the margin of the excision with greater precision than any alternative treatment option, while sparing healthy brain tissue from unnecessary and potentially damaging radiation exposure.

The applicant also stated that, when compared to other types of brain brachytherapy, GammaTile™ uses a new and unique mechanism of action to achieve a therapeutic outcome. The applicant explained that cancerous cells at the margins of a tumor resection cavity can also be irradiated with the placement of brachytherapy sources in the tumor cavity. However, the applicant asserted that the GammaTile™ technology is a pioneering form of brachytherapy for the treatment of brain tumors that uses the isotope cesium-131 embedded in a collagen implant that is customized to the geometry of the brain cavity. According to the applicant, the use of cesium-131 and the custom distribution of seeds offset in a three-dimensional collagen matrix results in a unique and highly effective delivery of radiation therapy to brain tissue. Specifically, the applicant asserted that the offset radiation source permits only a prescribed radiation dose to reach the target surface, reducing the potential for radiation induced necrosis and the need for reoperation. Additionally, the applicant stated that because the half-life of cesium-131 used in GammaTile™ is shorter compared to other brachytherapy isotopes, this results in a more rapid and effective energy deposition than other isotopes with longer half-lives. Therefore, applicant believes that GammaTile™ is unique due to the greater relative biological effectiveness compared to other brachytherapy options.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the GammaTile™ technology is a treatment option for patients who have been diagnosed with brain tumors that progress locally after initial treatment with external beam radiation therapy, and cases involving this technology are assigned to the same MS–DRG (MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemotherapy Implant)) as other current treatment forms of brachytherapy and external beam radiation therapy.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that the GammaTile™ technology offers a treatment option for a patient population with limited, or no other, available treatment options. The applicant explained that treatment options for patients who have been

diagnosed with brain tumors that progress locally after initial treatment with external beam radiation therapy are limited, and there is no current standard-of-care in this setting. According to the applicant, surgery alone for recurrent tumors may provide symptom relief, but does not remove all of the cancerous cells. The applicant further stated that repeating external beam radiation therapy for adjuvant treatment is hampered by an increasing risk of brain injury because additional external beam radiation therapy will increase the total dose of radiation to brain tissue, as well as increase the total volume of irradiated brain tissue. Secondary treatment with external beam radiation therapy is often performed with a reduced and, therefore less effective, dose. The applicant stated that the technique of implanting cesium-131 seeds in a collagen matrix is currently only available to patients in one location and requires a high degree of expertise to implant. The manufacturing process of the GammaTile™ will greatly expand the availability of treatment beyond research programs at highly specialized cancer treatment centers.

Based on the above, the applicant concluded that the GammaTile™ technology is not substantially similar to other existing technologies and meets the newness criterion.

However, we are concerned that the mechanism of action of the GammaTile™ may be the same or similar to current forms or radiation therapy or brachytherapy. Specifically, while the placement of the cesium-131 source (or any radioactive source) in a collagen matrix offset may constitute a new delivery vehicle, we are concerned that this sort of improvement in brachytherapy for the use in the salvage treatment of radiosensitive malignancies of the brain may not represent a new mechanism of action. We also question whether the technology treats a new patient population, as maintained by the applicant, because of the availability of other implantable treatment devices that treat the same patient population as the patients treated by the GammaTile™.

We are inviting public comments on whether the GammaTile™ technology is substantially similar to any existing technologies and whether it meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis. The applicant worked with the Barrow Neurological Institute at St. Joseph's Hospital and Medical Center (St. Joseph's) to obtain actual claims from mid-2015 through mid-2016 for craniotomies that did not involve placement of the GammaTile™ technology. The cases were assigned to MS–DRGs 025 through 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively). For the 460 claims, the average case-weighted unstandardized charge per case was $143,831. The applicant standardized the charges for each case and inflated each case's charges by applying the outlier charge inflation factor of 1.04205 included in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41718) by the age of each case (that is, the factor was applied to 2015 claims 3 times and 2016 claims 2 times). The applicant then calculated an estimate for ancillary charges associated with placement of the GammaTile™ device, as well as standardized charges for the GammaTile™ device itself. The applicant determined it meets the cost criterion because the final inflated average case-weighted standardized charge per case (including the charges associated with the GammaTile™ device) of $253,876 exceeds the average case-weighted threshold amount of $143,749 for MS–DRG 023, the MS–DRG that would be assigned for cases involving the GammaTile™ device.

The applicant also noted, in response to a concern expressed by CMS in the FY 2018 IPPS/LTCH PPS proposed rule, that its analysis does not include a reduction in costs due to reduced operating room times. The applicant stated that, while the use the device will reduce operating times relative to the freehand placement of seeds in other brain brachytherapy procedures, none of the claims in the cost analysis involve such freehand placement. We are inviting public comments on whether the GammaTile™ technology meets the cost criterion.

With regard to substantial clinical improvement, the applicant stated that the GammaTile™ technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments for recurrent CNS malignancies and significantly improves clinical outcomes when compared to currently available treatment options. The applicant explained that therapeutic options for patients who have been diagnosed with large or recurrent brain metastases are limited (for example, stereotactic radiotherapy, additional EBRT, or systemic immunochemotherapy). However, according to the applicant, the GammaTile™ technology provides a treatment option for patients who have been diagnosed with radiosensitive recurrent brain tumors that are not eligible for treatment with any other currently available treatment option. Specifically, the applicant stated that the GammaTile™ device may provide the only radiation treatment option for patients who have been diagnosed with tumors located close to sensitive vital brain sites (for example, brain stem) and patients who have been diagnosed with recurrent brain tumors who may not be eligible for additional treatment involving the use of external beam radiation therapy. There is a lifetime limit for the amount of radiation therapy a specific area of the body can receive. Patients whose previous treatment includes external beam radiation therapy may be precluded from receiving high doses of radiation associated with subsequent external beam radiation therapy, and the GammaTile™ technology can also be used to treat tumors that are too large for treatment with external beam radiation therapy. Patients who have been diagnosed with these large tumors are not eligible for treatment with external beam radiation therapy because the radiation dose to healthy brain tissue would be too high.

The applicant summarized how the GammaTile™ technology improves clinical outcomes compared to existing treatment options, including external beam radiation therapy and other forms of brain brachytherapy as: (1) Providing a treatment option for patients with no other available treatment options; (2) reducing the rate of mortality compared to alternative treatment options; (3) reducing the rate of radiation necrosis; (4) reducing the need for re-operation; (5) reducing the need for additional hospital visits and procedures; and (6) providing more rapid beneficial resolution of the disease process treatment.

The applicant cited several sources of data to support these assertions. The applicant referenced a paper by Brachman, Dardis et al., which was published in the *Journal of Neurosurgery* on December 21, 2018.[265] This study, a follow-up on the progress of 20 patients with recurrent previously irradiated meningiomasis, is a feasibility or superior progression-free survival study comparing the patient's own historical control rate against subsequent treatment with GammaTile™.

An additional source of clinical data is from Gamma Tech's internal review of data from two centers treating brain tumors with GammaTile™; the two

[265] Brachman, D., et al., ''Resection and permanent intracranial brachytherpay using modular, biocompatible cesium-131 implants: Results in 20 recurrent previously irradiated meningiomas,'' *J Neurosurgery,* December 21, 2018.

centers are the Barrow Neurological Institute (BNI) at St. Joseph's Hospital and St. Joseph's Medical Center, Phoenix, AZ, and this internal review is referred to herein as the ''BNI'' study.[266] The BNI study summarized Gamma Tech's experience with the GammaTile™ technology. Another source of data that the applicant cited to support its assertions regarding substantial clinical improvement is an abstract by Pinnaduwage, D., et al. Also submitted in the application were abstracts from 2014 through 2018 in which updates from the progression-free survival study and the BNI study were presented at specialty society clinical conferences. The following summarizes the findings cited by the applicant to support its assertions regarding substantial clinical improvement.

Regarding the assertion of local control, the 2018 article which was published in the *Journal of Neurosurgery* found that, with a median follow-up of 15.4 months (range 0.03–47.5 months), there were 2 reported cases of recurrence out of 20 meningiomas, with median treatment site progression time after surgery and brachytherapy with the GammaTile™ precursor and prototype devices not yet being reached, compared to 18.3 months in prior instances. Median overall survival after resection and brachytherapy was 26 months, with 9 patient deaths. In a presentation at the Society for Neuro-Oncology in November 2014,[267] the outcomes of 20 patients who were diagnosed with 27 tumors covering a variety of histological types treated with the GammaTile™ prototype were presented. The applicant noted the following with regard to the patients: (1) All tumors were intracranial, supratentorial masses and included low and high-grade meningiomas, metastases from various primary cancers, high-grade gliomas, and others; (2) all treated masses were recurrent following treatment with surgery and/or radiation and the group averaged two prior craniotomies and two prior courses of external beam radiation treatment; and (3) following surgical excision, the prototype GammaTile™ were placed in the resection cavity to deliver a dose of 60 Gray to a depth of 5 mm of tissue; and (4) all patients had previously experienced regrowth of their tumors at the site of treatment and the local control rate of patients entering the study was 0 percent.

With regard to outcomes, the applicant stated that, after their initial treatment, patients had a median progression-free survival time of 5.8 months; post treatment with the prototype GammaTile™, at the time of this analysis, only 1 patient had progressed at the treatment site, for a local control rate of 96 percent; and median progression-free survival time, a measure of how long a patient lives without recurrence of the treated tumor, had not been reached (as this value can only be calculated when more than 50 percent of treated patients have failed the prescribed treatment).

The applicant also cited the findings from Brachman, et al. to support local control of recurrent brain tumors. At the Society for Neuro-Oncology Conference on Meningioma in June 2016,[268] a second set of outcomes on the prototype GammaTile™ was presented. This study enrolled 16 patients with 20 recurrent Grade II or III meningiomas, who had undergone prior surgical excision external beam radiation therapy. These patients underwent surgical excision of the tumor, followed by adjuvant radiation therapy with the prototype GammaTile™. The applicant noted the following outcomes: (1) Of the 20 treated tumors, 19 showed no evidence of radiographic progression at last follow-up, yielding a local control rate of 95 percent; 2 of the 20 patients exhibited radiation necrosis (1 symptomatic, 1 asymptomatic); and (2) the median time to failure from the prior treatment with external beam radiation therapy was 10.3 months and after treatment with the prototype GammaTile™ only 1 patient failed at 18.2 months. Therefore, the median treatment site progression-free survival time after the prototype GammaTile™ treatment had not yet been reached (average follow-up of 16.7 months, range 1 to 37 months).

A third prospective study was accepted for presentation at the November 2016 Society for Neuro-Oncology annual meeting.[269] In this study, 13 patients who were diagnosed with recurrent high-grade gliomas (9 with glioblastoma and 4 with Grade III astrocytoma) were treated in an identical manner to the cases described above. Previously, all patients had failed the international standard treatment for high-grade glioma, a combination of surgery, radiation therapy, and chemotherapy referred to as the ''Stupp regimen.'' For the prior therapy, the median time to failure was 9.2 months (range 1 to 40 months). After therapy with a prototype GammaTile™, the applicant noted the following: (1) The median time to same site local failure had not been reached and 1 failure was seen at 18 months (local control 92 percent); and (2) with a median follow-up time of 8.1 months (range 1 to 23 months) 1 symptomatic patient (8 percent) and 2 asymptomatic patients (15 percent) had radiation-related MRI changes. However, no patients required re-operation for radiation necrosis or wound breakdown. Dr. Youssef was accepted to present at the 2017 Society for Neuro-Oncology annual meeting, where he provided an update of 58 tumors treated with the GammaTile™ technology. At a median whole group follow-up of 10.8 months, 12 patients (20 percent) had a local recurrence at an average of 11.33 months after implant. Six and 18 month recurrence free survival was 90 percent and 65 percent, respectively. Five patients had complications, at a rate that was equal to or lower than rates previously published for patients without access to the GammaTile™ technology.

In support of its assertion of a reduction in radiation necrosis, the applicant also included discussion of a presentation by D.S. Pinnaduwage, Ph.D., at the August 2017 annual meeting of the American Association of Physicists in Medicine. Dr. Pinnaduwage compared the brain radiation dose of the GammaTile™ technology with other radioactive seed sources. Iodine-125 and palladium-103 were substituted in place of the cesium-131 seeds. The study reported findings that other radioactive sources reported higher rates of radiation necrosis and that ''hot spots'' increased with larger tumor size, further limiting the use of these isotopes. The study concluded that the larger high-dose volume with palladium-103 and iodine-125 potentially increases the risk for radiation necrosis, and the inhomogeneity becomes more pronounced with increasing target volume. The applicant also cited a presentation by Dr. Pinnaduwage at the August 2018 annual meeting of the American Association of Physicists in Medicine, in which research findings demonstrated that seed migration in

[266] Brachman, D., et al., ''Surgery and Permanent Intraoperative Brachytherapy Improves Time to Progress of Recurrent Intracranial Neoplasms,'' Society for Neuro-Oncology Conference on Meningioma, June 2016.

[267] Dardis, C., ''Surgery and Permanent Intraoperative Brachytherapy Improves Times to Progression of Recurrent Intracranial Neoplasms,'' Society for Neuro-Oncology, November 2014.

[268] Brachman, D., et al, ''Surgery and Permanent Intraoperative Brachytherapy Improves Time to Progress of Recurrent Intracranial Neoplasms,'' Society for Neuro-Oncology Conference on Meningioma, June 2016.

[269] Youssef, E., ''C–131 Implants for Salvage Therapy of Recurrent High Grade Gliomas,'' Society for Neuro-Oncology Annual Meeting, November 2016.

collagen tile implantations was relatively small for all tested isotopes, with Cesium-13 showing the least amount of seed migration.

The applicant asserted that, when considered in total, the data reported in these presentations and studies and the intermittent data presented in their abstracts support the conclusion that a significant therapeutic effect results from the addition of GammaTile™ radiation therapy to the site of surgical removal. According to the applicant, the fact that these patients had failed prior best available treatments (aggressive surgical and adjuvant radiation management) presents the unusual scenario of a salvage therapy outperforming the current standard-of-care. The applicant noted that follow-up data continues to accrue on these patients.

Regarding the assertion that GammaTile™ reduces mortality, the applicant stated that the use of the GammaTile™ technology reduces rates of mortality compared to alternative treatment options. The applicant explained that studies on the GammaTile™ technology have shown improved local control of tumor recurrence. According to the applicant, the results of these studies showed local control rates of 92 percent to 96 percent for tumor sites that had local control rates of 0 percent from previous treatment. The applicant noted that these studies also have not reached median progression-free survival time with follow-up times ranging from 1 to 37 months. Previous treatment at these same sites resulted in median progression-free survival times of 5.8 to 10.3 months.

The applicant further stated that the use of the GammaTile™ technology reduces rates of radiation necrosis compared to alternative treatment options. The applicant explained that the rate of symptomatic radiation necrosis in the GammaTile™ clinical studies of 5 to 8 percent is substantially lower than the 26 percent to 57 percent rate of symptomatic radiation necrosis requiring re-operation historically associated with brain brachytherapy, and lower than the rates reported for initial treatment of similar tumors with modern external beam and stereotactic radiation techniques. The applicant indicated that this is consistent with the customized and ideal distribution of radiation therapy provided by the GammaTile™ technology.

The applicant also asserted that the use of the GammaTile™ technology reduces the need for re-operation compared to alternative treatment options. The applicant explained that patients receiving a craniotomy, followed by external beam radiation therapy or brachytherapy, could require re-operation in the following three scenarios:

- Tumor recurrence at the excision site could require additional surgical removal;
- Symptomatic radiation necrosis could require excision of the affected tissue; and
- Certain forms of brain brachytherapy require the removal of brachytherapy sources after a given period of time.

However, according to the applicant, because of the high local control rates, low rates of symptomatic radiation necrosis, and short half-life of cesium-131, the GammaTile™ technology will reduce the need for re-operation compared to external beam radiation therapy and other forms of brain brachytherapy.

Additionally, the applicant stated that the use of the GammaTile™ technology reduces the need for additional hospital visits and procedures compared to alternative treatment options. The applicant noted that the GammaTile™ technology is placed during surgery, and does not require any additional visits or procedures. The applicant contrasted this improvement with external beam radiation therapy, which is often delivered in multiple fractions that must be administered over multiple days. The applicant provided an example where whole brain radiotherapy (WBRT) is delivered over 2 to 3 weeks, while the placement of the GammaTile™ technology occurs during the craniotomy and does not add any time to a patient's recovery.

Based on consideration of all of the data presented above, the applicant believed that the use of the GammaTile™ technology represents a substantial clinical improvement over existing technologies.

We are concerned that the clinical efficacy and safety data provided by the applicant may be limited. The findings presented appear to be derived from relatively small case-studies and not data from FDA approved clinical trials. While the applicant described increases in median time to disease recurrence in support of clinical improvement, we are concerned with the lack of analysis, meta-analysis, or statistical tests that indicated that seeded brachytherapy procedures represented a statistically significant improvement over alternative treatments, such as external beam radiation or other forms of brachytherapy. We also are concerned with the lack of studies involving the actual manufactured device. Finally, while the FDA cleared GammaTile™ under section 510(k), authorization to market the device for the cleared indications, we note that the FDA's issuance of a ''substantially equivalent determination'' did not indicate a review of any specific superiority claims to a predicate device.

We are inviting public comments on whether the GammaTile™ technology meets the substantial clinical improvement criterion. We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for GammaTile™ or at the New Technology Town Hall meeting.

m. Imipenem, Cilastatin, and Relebactam (IMI/REL) Injection

Merck & Co., Inc. submitted an application for new technology add-on payments for IMI/REL for FY 2020. The applicant is seeking an indication for IMI/REL for the treatment of patients 18 years of age and older who have been diagnosed with: (a) Complicated intra-abdominal infections (cIAI) caused by susceptible gram-negative microorganisms where limited or no alternative therapies are available; and (b) complicated urinary tract infections (cUTIs), including pyelonephritis, caused by susceptible gram-negative microorganisms where limited or no alternative therapies are available. The applicant stated that IMI/REL does not currently have a trade name, although an NDA was accepted and is being reviewed for IMI/REL.

The applicant reported that complicated intra-abdominal infections are a subset of intra-abdominal infections, a term which includes a diverse set of diseases. It is broadly defined as peritoneal inflammation in response to micro-organisms, resulting in purulence in the peritoneal cavity. Complicated intra-abdominal infections extend beyond the source organ into the peritoneal space. These infections cause peritoneal inflammation, and are associated with localized or diffuse peritonitis. Localized peritonitis often manifests as an abscess with tissue debris, bacteria, neutrophils, macrophages, and exudative fluid contained in a fibrous capsule. Diffuse peritonitis is categorized as primary, secondary, or tertiary peritonitis.[270]

In addition, the applicant stated that complicated intra-abdominal infections

[270] Lopez, N., Kobayashi, L., Coimbra, R., ''A Comprehensive review of abdominal infections,'' *World J Emerg Surg,* 2011, vol. 6, pp. 7, Published February 23, 2011, doi:10.1186/1749–7922–6–7.

are characterized by chills, rigors, or fever (temperature of greater than or equal to 38.0 °C); elevated white blood cell count (greater than 10,000/mm^3), or left shift (greater than 15 percent immature PMNs); nausea or vomiting; dysuria, increased urinary frequency, or urinary urgency; and lower abdominal pain or pelvic pain. Acute pyelonephritis is characterized by chills, rigors, or fever (temperature of greater than or equal to 38.0 °C); elevated white blood cell count (greater than 10,000/mm^3), or left shift (greater than 15 percent immature PMNs); nausea or vomiting; dysuria, increased urinary frequency, or urinary urgency; flank pain; and costo-vertebral angle tenderness on physical examination. Risk factors for infection with drug-resistant organisms do not, on their own, indicate a cUTI.[271]

According to the applicant, IMI/REL is a fixed-dose combination of imipenem/cilastatin (IMI), a β-lactam (BL) antibacterial (specifically, a carbapenem), and relebactam (REL), a novel β-lactamase inhibitor (BLI). The applicant stated that IMI was the first marketed carbapenem when approved by the FDA in 1985. It is a sterile formulation of imipenem (a thienamycin antibacterial) and cilastatin sodium (inhibitor of the renal dipeptidase, dehydropeptidase-l). The applicant asserted that IMI is stable against hydrolysis by many extended spectrum β-lactamases (ESBLs) and is frequently used for the treatment of serious bacterial infections in which gram-negative bacteria and/or anaerobes play a significant role. The applicant additionally stated that REL is a non-β-lactam, small molecule diazabicyclooctane (DABCO) BLI with inhibitory activity against various β-lactamases: Class A carbapenemases (such as KPC), Class C cephalosporinases (including AmpC), and ESBLs.

The applicant stated that procedures involving the administration of IMI/REL could be, generally, identified with ICD–10–PCS codes 3E03329 (Introduction of other anti-infective into peripheral vein, percutaneous approach) or 3E04329 (Introduction of other anti-infective into central vein, percutaneous approach). However, neither code would uniquely identify procedures involving the administration of IMI/REL. The applicant has submitted a request to the ICD–10 Coordination and Maintenance Committee for approval for an ICD–10–PCS procedure code to distinctly identify procedures involving the administration of IMI/REL.

The applicant anticipates that the recommended dosage of IMI/REL will be 500 mg imipenem/500 mg cilastatin/250 mg relebactam, via intravenous infusion over 30 minutes every 6 hours. The applicant anticipates that the dosage will be decreased proportionally with decreases in the renal creatinine clearance category.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether the product uses the same or a similar mechanism of action as an existing technology to achieve the same therapeutic outcome, the applicant stated that IMI/REL's mechanism of action differentiates it from other approved injectable antibiotics. The applicant noted that there are three other BL/BLI antibiotics that have recently been FDA-approved, including Zerbaxa®, Avycaz®, and VABOMERE™. However, the applicant stated that the properties of REL, a non-β-lactam, small molecule diazabicyclooctane (DABCO) BLI with inhibitory activity against various β-lactamases including: Class A carbapenemases (such as KPC), Class C cephalosporinases (including AmpC), and ESBLs, when combined with imipenem and cilastatin, used as β-lactams, gives IMI/REL a different mechanism of action from that of the aforementioned BL/BLI antibiotics. The applicant provided comparisons of efficacy with other BL/BLI antibiotics as evidence of IMI/REL's unique mechanism of action, and asserted that the combination of REL and IMI would be efficacious in most imipenem-resistant strains at clinically achievable doses and concentrations, and that both IMI and REL are not subject to efflux pumps in *P. aeruginosa.* The applicant additionally submitted several studies that noted that REL, as a non-β-lactam, small-molecule BLI with dual Class A/C activity, is suited to inactivate β-lactamase subtypes involved in carbapenem resistance.[272] [273] By inhibiting these β-lactamases, the applicant claims that REL has the potential to restore IMI's efficacy against MDR pathogens previously expressing resistance to IMI.

With respect to the second criterion, whether the product is assigned to the same or a different MS–DRG as existing technologies, the applicant asserted that patients who may be eligible to receive treatment involving IMI/REL include hospitalized patients who have been diagnosed with a cUTI or cIAI. We expect that cases involving IMI/REL would most likely be assigned to the same MS–DRGs to which cases involving comparator treatments are assigned.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted that the use of IMI/REL would treat a different patient population than existing and currently available treatment options. As previously noted, the applicant submitted several studies that noted REL, as a non-β-lactam, small-molecule BLI with dual Class A/C activity, is suited to inactivate β-lactamase subtypes involved in carbapenem resistance.[274] [275] By inhibiting these β-lactamases, the applicant asserts that REL has the potential to restore IMI's efficacy against MDR pathogens previously expressing resistance to IMI and, therefore, to extend treatment to patient populations that might have previously been resistant to IMI. Additionally, the applicant compared the administration of IMI/REL to other comparator antibiotics to demonstrate its unique place in the armamentarium, beginning with three older antibiotics. First, in comparison to polymyxins, the applicant asserts that even in colistin-derived preparations of polymyxins, nephrotoxicity is still evident and is the potential adverse experience of most

[271] Hooton, T. and Kalpana, G., ''Acute complicated urinary tract infection (including pyelonephritis) in adults,'' In A. Bloom (Ed.), UpToDate. Available at: *https://www.uptodate.com/contents/acute-complicated-urinary-tract-infectionincluding-pyelonephritis-in-adults.*

[272] Sims, et al., ''Prospective, randomized, double-blind, Phase 2 dose-ranging study comparing efficacy and safety of imipenem/cilastatin plus relebactam with imipenem/cilastatin alone in patients with complicated urinary tract infections.'' *Journal of Antimicrobial Chemotherapy.* 2017.

[273] Rhee, et al., ''Pharmacokinetics, Safety, and Tolerability of Single and Multiple Doses of Relebactam, a b-LactamaseInhibitor, in Combination with Imipenem and Cilastatin in Healthy Participants.'' *Antimicrobial Agents and Chemotherapy,* 2018.

[274] Sims, et al., ''Prospective, randomized, double-blind, Phase 2 dose-ranging study comparing efficacy and safety of imipenem/cilastatin plus relebactam with imipenem/cilastatin alone in patients with complicated urinary tract infections.'' *Journal of Antimicrobial Chemotherapy,* 2017.

[275] Rhee, et al., ''Pharmacokinetics, Safety, and Tolerability of Single and Multiple Doses of Relebactam, a b-LactamaseInhibitor, in Combination with Imipenem and Cilastatin in Healthy Participants.'' *Antimicrobial Agents and Chemotherapy,* 2018.

concern to prescribing clinicians,[276] and further asserted that neither polymyxin B nor colistin have been subjected to contemporary drug development procedures.[277] Second, the applicant asserted that clinical data for fosfomycin in the treatment of MDR bacterial infections are very scarce. Third, the applicant stated that tigecycline does not have activity against *Pseudomonas* spp.[278] Furthermore, in a safety announcement released by the FDA in 2013, it was noted that an increased risk of death was observed with tigecycline compared to other antibacterials used to treat similar infections.[279]

The applicant also compared the administration of IMI/REL to the three other aforementioned BL/BLI antibiotics. First, the applicant asserted that the use of tazobactam in Zerbaxa® is not effective against KPC-producing bacteria [280] and some highly drug-resistant strains of *P. aeruginosa,* including some carbapenem-resistant (CR) strains, which are able to escape the antipseudomonal activity of Zerbaxa®. Second, the applicant asserted that there have been recent reports of resistance to Avycaz®,[281] [282] including in a recent report published by the European Centre for Disease Prevention and Control (ECDC).[283] The applicant reports that additionally, avibactam has been shown to be subject to efflux in *P. aeruginosa,* which the applicant asserts casts further concerns regarding its utility.[284] [285] Third, the applicant asserted that the use of vaborbactam in VABOMERE™ has little impact on the activity of meropenem *in vitro* against CR *P. aeruginosa,* arguably due to vaborbactam being subject to efflux.[286] [287] In addition, the applicant stated that the U.S. Prescribing Information (USPI) for VABOMERE™ indicates that vaborbactam has no effect on meropenem activity against meropenem-susceptible isolates.[288]

Finally, the applicant compared the administration of IMI/REL to two additional antibiotics. First, the applicant asserted that Xerava™ has no activity against *P. aeruginosa.*[289] Second, the applicant asserted that aminoglycosides, including Zemdri™, usually have minimal lung penetration, limiting potential efficacy in HABP/VABP. The applicant stated that currently used aminoglycosides are associated with nephrotoxicity and ototoxicity, and, outside of UTI, are rarely given as single agents in the treatment of serious bacterial infections. The applicant stated that the approved USPI for Zemdri™ includes black-box warnings for nephrotoxicity, ototoxicity, neuromuscular blockade, and fetal harm.[290]

We are concerned that the mechanism of action of IMI/REL may be similar to the mechanism of action of other BL/BLI antibiotics. While we recognize that REL is used as a unique molecular structure with respect to other BLIs in BL/BLI combination, the fundamental mechanism of action of IMI/REL may be similar to that of other BL/BLIs. Additionally, with respect to whether the use of IMI/REL would treat a different patient population than existing treatment options, we note that, while the variety of antibiotic resistance-patterns certainly warrants a varied armamentarium for clinicians, there are existing antimicrobials that are approved to, generally, treat diagnoses of cUTIs, cIAIs, and MDR pathogens. We are concerned that non-uniform resistance patterns among patients, necessitating a range of drugs to treat the same diseases, may not constitute a new patient population. We are inviting public comments on whether the IMI/REL technology is substantially similar to any existing technologies and whether it meets the newness criterion, including with respect to the concerns we have raised.

The applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. To determine the MS–DRGs that potential cases representing patients who may be eligible for treatment involving the administration of IMI/REL would map to, the applicant identified all MS–DRGs containing cases that reported ICD–10–CM diagnosis codes for cUTI or cIAI, as a primary or secondary diagnosis, as well as a diagnosis code(s) for CRE resistance. Based on the FY 2017 MedPAR data file and Hospital Limited Data Set (LDS), the applicant identified a total of 21,111 cases representing patients who may be eligible for treatment with the administration of IMI/REL, which mapped to 441 unique MS–DRGs. There were 307 MS–DRGs with very minimal frequencies (fewer than 11 cases), and a total of 1,138 cases associated with these low-volume MS–DRGs. After trimming the cases that were mapped to low-volume MS–DRGS, the applicant identified 19,973 cases that were mapped to 134 unique MS–DRGs, with the top 10 MS–DRGs covering approximately 74.3 percent of all identified cases.

Using 100 percent of the 19,973 cases considered, the applicant determined an average case-weighted unstandardized charge per case of $60,506. The applicant standardized the charges for each case and inflated each case's charges by applying the FY 2019 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.08864 (83 FR 41722). (We note that this 2-year charge inflation factor was revised in the FY 2019 IPPS/LTCH PPS final rule correction notice. The corrected factor is 1.08986 (83 FR 49844). However, we further note that even when using the corrected final rule values to inflate the

[276] Dalfino, L, et al., ''High-Dose, extended-interval colistin administration in critically ill patients: is this the right dosing strategy? A preliminary study,'' *Clin Infect Dis,* 2012, vol. 54(12), pp. 1720–6.

[277] American Thoracic Society, Infectious Diseases Society of America, ''Guidelines for the management of adults with hospital lacquired, ventilator-associated, and healthcare-associated pneumonia,'' *Am J Respir Crit Care Med,* 2005, vol. 171, pp. 388–416.

[278] Giamarellou, H., Poulakou, G., ''Multidrug-resistant gram-negative infections; what are the treatment options? Drugs,'' *Drugs,* 2009, vol, 69(14), pp. 1879–1901.

[279] FDA Drug Safety Communication: ''FDA warns of increased risk of death with IV antibacterial Tygacil (tigecycline) and approves new Boxed Warning'', Accessed at *https://www.fda.gov/Drugs/DrugSafety/ucm369580.htm* on 11/10/2018.

[280] Papp-Wallace, K.M., et al., ''Substrate selectivity and a novel role in inhibitor discrimination by residue 237 in the KPC–2 betalactamase,'' *Antimicrob Agents Chemother,* Jul 2010, vol. 54(7). pp. 2867–77, doi: 10.1128/AAC.00197–10, Epub 2010, Apr 26.

[281] Shields, R.K., et al., ''Emergence of ceftazidime-avibactam resistance due to plasmid-borne blaKPC–3 mutations during treatment of carbapenem-resistant *Klebsiella pneumoniae* infections,'' *Antimicrob Agents Chemother,* Feb 23, 2017, vol. ;61(3), pii: e02097–16, doi: 10.1128/AAC.02097–16, Print 2017 Mar.

[282] Haidar, G,, et al., ''Identifying spectra of activity and therapeutic niches for ceftazidime-avibactam and imipenem relebactam against carbapenemresistant Enterobacteriaceae,'' *Antimicrob Agents Chemother,* 2017, vol. 61, pp. e00642–17.

[283] European Centre for Disease Prevention and Control, ''Emergence of resistance to ceftazidime-avibactam in carbapenem-resistant Enterobacteriaceae, 12 June 2018,'' Stockholm; ECDC; 2018.

[284] Poster presented at ECCMID 2017 (Apr 22–25), Vienna (Austria). EP0469: Avibactam is a substrate for MexAB-OprM in *P.aeruginosa.*

[285] Chalhoub, H., et al., ''Loss of activity of ceftazidime-avibactam due to Mex-AB-OprM efflux and overproduction of AmpC cephalosporinase in *Pseudomonas aeruginosa* isolated from patients suffering from cystic fibrosis,'' *Int J Antimicrob Agents,* August 3, 2018, pii: S0924–8579(18)30226–7, doi: 10.1016/j.ijantimicag.2018.07.027. [Epub ahead of print].

[286] Castanheira, M., et al., ''Meropenem-Vaborbactam Tested against contemporary gram-negative isolates collected worldwide during 2014, including carbapenem-resistant, KPC-producing, multidrug-resistant, and extensively drug-resistant Enterobacteriaceae,'' *Antimicrob Agents Chemother.* August, 24, 2017, vol. 61(9), pii: e00567–17, doi: 10.1128/AAC.00567–17, Print September 2017.

[287] Zhanel, G.G., et al., ''Imipenem-relebactam and meropenem-vaborbactam: two novel carbapenem-β-lactamase inhibitor combinations,'' *Drugs,* January 2018, vol. 78(1), pp. 65–98, doi: 10.1007/s40265–017–0851–9.

[288] USPI for VABOMERE™.

[289] USPI for Xerava™.

[290] USPI for Zemdri™.

charges, the average case-weighted standardized charge per case for each scenario exceeded the average case-weighted threshold amount.) The applicant then removed 100 percent of the drug charges from the relevant cases to estimate the charges for drugs that potentially may be replaced or avoided by the administration of IMI/REL. The applicant then added charges for the administration of IMI/REL by taking the cost of the drug and converting it to a charge by dividing the costs by the national average CCR of 0.191 for drugs from the FY 2019 IPPS/LTCH PPS final rule (83 FR 41273). The applicant calculated an average case-weighted standardized charge per case of $74,778, using the percent distribution of MS–DRGs as case-weights. Based on this analysis, the applicant determined that the final inflated average case-weighted standardized charge per case for cases involving the administration of IMI/REL exceeded the average case-weighted threshold amount of $50,417 by $24,361.

The applicant conducted additional analysis to demonstrate that the technology meets the cost criterion. In these analyses, the applicant repeated the cost analysis above with one analysis of cases with a diagnosis of cUTI and the other analysis of cases with a diagnosis of cIAI. In each of these additional sensitivity analyses, the applicant determined that the final inflated average case-weighted standardized charge per case exceeded the final average case-weighed threshold amount, by $21,677 and $44,119, respectively. We are inviting public comments on whether the administration of IMI/REL meets the cost criterion.

With regard to substantial clinical improvement, the applicant believes that the administration of IMI/REL represents a substantial clinical improvement over currently available therapies because of the efficacy and safety results of the completed Phase III trial RESTORE–IMI 1. RESTORE–IMI 1 included 47 subjects who were randomized in a randomized, double-blind, active-controlled, parallel group, multi-center Phase III trial of IMI/REL (provided together in a single vial as a fixed-dose combination product) + placebo compared with colistin (in the form of colistimethate sodium [CMS]) + IMI in patients with imipenem non-susceptible bacterial infections, including HABP/VABP, cIAI, and cUTI. The primary efficacy endpoint for RESTORE–IMI 1 was overall response based on the following: (a) All-cause mortality through Day 28 post-randomization in patients who had been diagnosed with HABP/VABP, (b) clinical response at Day 28 post-randomization for patients who had been diagnosed with cIAI, and (c) composite clinical and microbiological response at early follow-up (EFU) (Day 5 to 9 following completion of therapy) for patients who had been diagnosed with cUTI. Key secondary efficacy endpoints include estimation of clinical response at Day 28 post-randomization and all-cause mortality through Day 28. A favorable clinical response for all infection sites refers to resolution of baseline clinical signs and symptoms associated with the baseline infection. The primary efficacy analysis population for this study is the microbiological modified intent-to treat (m-MITT) population (31 patients), defined as all randomized patients who received at least one dose of the study drug within a given stage/phase IV study therapy regimen, and who had been diagnosed with a qualifying baseline bacterial pathogen.

With respect to efficacy, the applicant stated that the administration of IMI/REL demonstrates a substantial clinical improvement due to the following three study results: (1) Numerically comparable overall response of the use of IMI/REL compared to CMS + IMI, (2) numerically favorable clinical response at Day 28 for the use of IMI/REL compared to CMS + IMI, and (3), numerically lower all-cause mortality at Day 28. First, the applicant indicated that a favorable overall response (primary endpoint) was achieved in 71.4 percent of the patients who received treatment involving IMI/REL + placebo and 70.0 percent of the patients who received treatment with CMS + IMI.[291] Second, the applicant asserted that favorable clinical response (secondary endpoint) was achieved by a higher percentage of the patients who received treatment involving IMI/REL + placebo (71.4 percent) than patients who received treatment with CMS + IMI (40.0 percent) at Day 28, as well as at all other time points assessed.[292] Third, the applicant states that all-cause mortality at Day 28 favored IMI/REL + placebo (9.5 percent) over CMS + IMI (30 percent), although the difference was not statistically significant at the 90 percent level.

With respect to safety, the applicant indicated that the primary population used for all safety evaluations was the All-Subjects-as-Treated (ASaT) population, which comprises all patients who received at least one dose of the study medication. The applicant stated that the incidence of AEs, including deaths, SAEs, drug-related AEs and SAEs, and discontinuations due to AEs, was lower in patients who received treatment involving the administration of IMI/REL + placebo than in patients who received treatment involving the CMS + IMI. Overall, the most commonly reported AEs (greater than or equal to 10 percent of the patients overall) across both treatment groups were pyrexia (12.8 percent of the patients), increased AST (12.8 percent of the patients), increased ALT (10.6 percent), and nausea (10.6 percent of subjects). The incidences of increased AST, increased ALT, and nausea were lower in patients who received treatment involving IMI/REL + placebo than in patients who received treatment involving CMS + IMI. The applicant further stated that in accounting for nephrotoxicity associated with the use of CMS, a pre-specified key secondary objective of the study was to estimate the proportion of patients who experienced treatment-emergent nephrotoxicity following receipt of treatment involving IMI/REL + placebo or CMS + IMI and to compare the treatment groups. From this analysis, the applicant concluded that the incidence of treatment-emergent nephrotoxicity was significantly lower in patients who received treatment involving IMI/REL + placebo (10.3 percent) than in patients who received treatment involving CMS + IMI (56.3 percent) (two-sided p-value of 0.002).

We have the following concerns regarding whether IMI/REL meets the substantial clinical improvement criterion. First, we are concerned regarding the comparator chosen for the RESTORE–IMI 1 trial. We are not certain why the combination of CMS + IMI was chosen, and if other comparators would have been more appropriate. Second, 8 of the 21 cases in the m-MITT population treated with IMI/REL were cases of HABP/VABP,[293] and further 7 out of the 15 cases of positive clinical response in the m-MITT population to IMI/REL were cases of HABP/VABP.[294] Because HABP/VABP are not conditions for which the applicant is seeking indications for IMI/REL, it is possible that conclusions drawn from the RESTORE–IMI 1 study regarding safety and efficacy are not specific to those indications described

[291] Motsch, J. et al., ''RESTORE–IMI 1: A Multicenter, Randomized, Double-Blind, Comparator-Controlled Trial Comparing the Efficacy and Safety of Imipenem/Relebactam vs Colistin Plus Imipenem in Patients With Imipenem–Non-susceptible Bacterial Infections.''

[292] Ibid.

[293] 18–1315–D MRPAB18303 IDWeek SmMITT_final.

[294] Ibid.

in the application. Third, the favorable clinical response after Day 28 is measured at the 90 percent confidence level,[295] rather than the more common 95 percent level, without explanation. Fourth, we note that the study is composed of an initial sample of only 47 patients.[296] With such a small sample we are concerned about the external validity of the conclusions, specifically the generalizability of the results to the Medicare population, given the specific demographic makeup of that population. Fifth, we have another methodological concern regarding the different endpoints present in the study, along with the Day 28 assessment. We note that HABP/VABP, cUTI, and cIAI are measured respectively by mortality, favorable clinical response (cure), and favorable clinical response (cure OR sustained eradication).[297] We are uncertain why different endpoints were chosen for the different conditions. Additionally, we are uncertain if the Day 28 assessment cited in the application reflects microbiological or just clinical response. Sixth, the applicant defined the m-MITT and ASaT populations as those patients who received at least one dose of the study drug. We are not certain whether these analyses should also include those patients in the comparator arm who did not receive the study drug, as this could violate the applicant's definition of m-MITT. Seventh, CMS also notes that both the estimated difference in the favorable overall response at the primary endpoint and the estimated difference in all-cause mortality are not statistically significant[298] and, therefore, may not represent a substantial clinical improvement. Finally, in addition, with respect to safety, the applicant asserted that the administration of IMI/REL induces less nephrotoxicity compared to the use of CMS + IMI. However, nephrotoxicity is a known adverse effect of CMS, and other available antimicrobials approved to treat diagnoses of cUTIs and cIAIs induce less nephrotoxicity (and were not studied in the data provided to support this application). Therefore, it is not clear that IMI/REL induces less nephrotoxicity compared to other available treatments.

We are inviting public comments on whether IMI/REL meets the substantial clinical improvement criterion, including with respect to the concerns we have raised. We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for IMI/REL or at the New Technology Town Hall meeting.

n. JAKAFI™ (Ruxolitinib)

Incyte Corporation submitted an application for new technology add-on payments for JAKAFI™ (ruxolitinib) for FY 2020. JAKAFI™ is an oral kinase inhibitor that inhibits Janus-associated kinases 1 and 2 (JAK1/JAK2). The JAK pathway, which includes JAK1 and JAK2, is involved in the regulation of immune cell maturation and function. According to the applicant, JAK inhibition represents a novel therapeutic approach for the treatment of acute graft-versus-host disease (GVHD) in patients who have had an inadequate response to corticosteroids.

Allogeneic hematopoietic stem cell transplantation (allo-HSCT) is a treatment option for patients who have been diagnosed with hematologic cancers, some solid tumors, and some non-malignant hematologic disorders. According to the applicant, approximately 9,000 allo-HSCTs were performed in the U.S. in 2017. The most common cause of death in allo-HSCT recipients within the first 100 days is relapsed disease (29 percent), infection (16 percent), and GVHD (9 percent).[299] GVHD is a condition where donor immunocompetent cells attack the host tissue. GVHD can be acute (aGVHD), which generally occurs prior to day 100, or chronic (cGVHD). aGVHD results in systemic inflammation and tissue destruction affecting multiple organs. Systemic corticosteroids are used as first-line therapy for the treatment of a diagnosis of aGVHD, with response rates between 40 percent and 60 percent. However, the response is often not durable, and there is no consensus on optimal second-line treatment.[300] The applicant envisions the use of JAKAFI™ as second-line treatment (that is, first-line steroid treatment failures) for the treatment of a diagnosis of steroid-refractory aGVHD.

The applicant reports that there are no FDA-approved treatments for patients who have been diagnosed with steroid-refractory aGVHD, and despite available treatment options, according to the applicant, patients do not always achieve a positive response, underscoring the need for new and innovative treatments for these patients. The applicant also states that patients who develop steroid-refractory aGVHD can progress to severe disease, with 1-year mortality rates of 70 to 80 percent. A number of combination treatment approaches are being investigated as second-line therapy in patients who have been diagnosed with steroid-refractory aGVHD, including methotrexate, mycophenolate mofetil, extracorporeal photopheresis, IL–2R targeting agents (basiliximab, daclizumab, denileukin, and diftitox), alemtuzumab, horse antithymocyte globulin, etancercept, infliximab, and sirolimus. According to the applicant, the American Society for Blood and Marrow Transplantation (ASBMT) does not provide any recommendations for second-line therapy for patients who have been diagnosed with steroid-refractory aGVHD, nor suggest avoidance of any specific agent.

JAKAFI™ received FDA approval in 2011 for the treatment of patients who have been diagnosed with intermediate or high-risk myelofibrosis (MF). In addition, JAKAFI™ received FDA approval in December 2014 for the treatment of patients who have been diagnosed with polycythemia vera (PV) who have had an inadequate response to, or are intolerant of hydroxyurea. JAKAFI™ is primarily prescribed in the outpatient setting for these indications. The applicant has submitted a supplemental new drug application (sNDA) (with Orphan Drug and Breakthrough Therapy designations) seeking FDA's approval for a new indication for JAKAFI™ for the treatment of patients who have been diagnosed with steroid-refractory aGVHD who have had an inadequate response to treatment with corticosteroids. The applicant asserts that for this new indication, JAKAFI™ is expected to be used in the inpatient setting, during either hospital admission for allo-HSCT, or upon need for hospital re-admission for treating patients who have been diagnosed with aGVHD who have had an inadequate response to treatment with corticosteroids. Although as of the time of the development of this FY 2020 IPPS/LTCH PPS proposed rule it has not yet received FDA approval, the applicant

[295] 18–1315–C MRPAB18304 IDWeek Nephrotoxicity_final.

[296] Ibid.

[297] 18–1315–D MRPAB18303 IDWeek SmMITT_final.

[298] Kaye, K.S., et al., ''Results for the Supplemental Microbiological Modified Intent-to-Treat (SmMITT) Population of the RESTORE–IMI 1 Trial of Imipenem/Cilastatin/Relebactam Versus Colistin Plus Imipenem/Cilastatin in Patients With Imipenem-Nonsusceptible.''

[299] D'Souza, A., Lee, S., Zhu, X., Pasquini, M., ''Current use and trends in hematopoietic cell transplantation in the United States,'' *Biol Blood Marrow Transplant,* 2017, vol. 23(9), pp. 1417–1421.

[300] Martin, P.J., Rizzo, J.D., Wingard, J.R., et al., ''First and second-line systemic treatment of acute graft-versus-host disease: recommendations of the American Society of Blood and Marrow Transplantation,'' *Biol Blood Marrow Transplant,* 2012, vol. 18(8), pp. 1150–1163.

indicated that it expects FDA approval for this new indication for the use of JAKAFI™ prior to the July 1, 2019 deadline.

There are currently no ICD–10–PCS procedure codes that uniquely identify the administration of JAKAFI™. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code to describe procedures involving the administration of JAKAFI™ beginning in FY 2020.

As stated above, if a technology meets all three of the substantial similarity criteria described above, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserts that there are no products that utilize the same or similar mechanism of action (that is, JAK inhibition) to achieve the same therapeutic outcome for the treatment of acute steroid-resistant GVHD. The applicant further explained that JAKAFI™ functions to inhibit the JAK pathway, and has been shown in pre-clinical and clinical trials to reduce GVHD. The applicant explained that JAKs are intracellular, non-receptor tyrosine kinases that relay the signaling of inflammatory cytokines. The applicant stated that, based on their role in immune cell development and function, JAKs might affect all phases of aGVHD pathogenesis, including cell activation, expansion, and destruction. Specifically, JAKs regulate activities of immune cells involved in aGVHD etiology, including antigen-presenting cells, T-cells, and B-cells, and function downstream of many cytokines relevant to GVHD-mediated tissue damage. Inhibition of JAK1/JAK2 signaling in aGVHD could be expected to block signal transduction from proinflammatory cytokines that activate antigen-presenting cells, expansion and differentiation of T-cells, suppression of regulatory T-cells, and inflammation and tissue destruction mediated by infiltrating cytotoxic T-cells.[301] The applicant stated that other agents that are being investigated as second-line treatments for patients who have been diagnosed with steroid-resistant aGVHD, such as methotrexate, mycophenolate mofetil, extracorporeal photopheresis, IL–2R targeting agents (basiliximab, daclizumab, denileukin, and diftitox), alemtuzumab, horse antithymocyte globulin, etancercept, infliximab, and sirolimus, use a different mechanism of action than that of JAKAFI™. The applicant believes that the mechanism of action of JAKAFI™ differs from that of existing technologies used to achieve the same therapeutic outcome.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant asserts that there are currently no FDA-approved medicines for the treatment of patients who have been diagnosed with steroid-refractory aGVHD who have had an inadequate response to corticosteroids and, therefore, JAKAFI™ would not be assigned to the same MS–DRG as existing technologies.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that there are no existing treatment options for patients who have been diagnosed with steroid-refractory aGVHD who have had an inadequate response to corticosteroids and, therefore, JAKAFI™ represents a new treatment option for a patient population without existing or alternative options. The applicant stated that, based on its knowledge, there are no other prospective studies evaluating the effects of treatment with JAK inhibitors for the treatment of aGVHD in this patient population, and there are no FDA-approved agents for the treatment of patients who have been diagnosed with steroid-refractory aGVHD who have inadequately responded to treatment with corticosteroids.

For the reasons summarized above, the applicant maintained that JAKAFI™ is not substantially similar to any existing technology. We note, however, that there are a number of available second-line treatment options for a diagnosis of aGVHD that treat the same patient population. We also note that a number of these treatment options use a method of immunomodulation and suppress the body's immune response similar to the mechanics and goals of JAKAFI™ and, therefore, we believe that JAFAKI™ may have a similar mechanism of action as existing therapies. Finally, for patients receiving treatment involving any current second-line therapies for a diagnosis of steroid-refractory aGVHD, CMS would expect these patient cases to be generally assigned to the same MS–DRGs as a diagnosis for aGVHD, as would cases representing patients who may be eligible for treatment involving JAKAFI™. We are inviting public comments on whether JAKAFI™ is substantially similar to any existing technologies, including with respect to the concerns we have raised, and whether the technology meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. To identify cases representing patients who may be eligible for treatment involving JAKAFI™, the applicant searched the FY 2017 MedPAR Limited Data Set (LDS) for cases reporting ICD–10–CM diagnosis codes for acute or unspecified GVHD in combination with either ICD–10–CM diagnosis codes for associated complications of bone marrow transplant or ICD–10–PCS procedure codes for transfusion of allogeneic bone marrow, as identified in the table below. The applicant used this methodology to capture patients who developed aGVHD during their initial stay for allo-HSCT treatment, as well as those patients who were discharged and needed to be readmitted for a diagnosis of aGVHD.

The applicant submitted the following table displaying a complete list of the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes it used to identify cases representing patients who may be eligible for treatment with JAKAFI™.

BILLING CODE 4120–01–P

[301] Martin, P.J., Rizzo, J.D., Wingard, J.R., et al., ''First and second-line systemic treatment of acute graft-versus-host disease: recommendations of the American Society of Blood and Marrow Transplantation,'' *Biol Blood Marrow Transplant,* 2012, vol. 18(8), pp. 1150–1163.

List of Diagnosis and Procedure Codes Used for Incyte JAKAFI™ Cost Analysis			
Group	**Code Type**	**Codes**	**Description**
Group 1: Acute or unspecified GVHD (Graft-versus-host disease)	ICD-10-CM Diagnosis Codes	D89.810	Acute graft-versus-host disease
		D89.812	Acute on chronic graft-versus-host disease
		D89.813	Graft-versus-host disease, unspecified
Group 2: Complications of bone marrow transplant	ICD-10-CM Diagnosis Codes	T86.00	Unspecified complication of bone marrow transplant
		T86.01	Bone marrow transplant rejection
		T86.02	Bone marrow transplant failure
		T86.03	Bone marrow transplant infection
		T86.09	Other complications of bone marrow transplant
Group 3: Transfusion of allogeneic bone marrow	ICD-10-PCS Procedure Codes	30230G2	Transfusion of allogeneic related bone marrow into peripheral vein, open approach
		30230G3	Transfusion of allogeneic unrelated bone marrow into peripheral vein, open approach
		30230G4	Transfusion of allogeneic unspecified bone marrow into peripheral vein, open approach
		30230X2	Transfusion of allogeneic related cord blood stem cells into peripheral vein, open approach
		30230X3	Transfusion of allogeneic unrelated cord blood stem cells into peripheral vein, open approach
		30230X4	Transfusion of allogeneic unspecified cord blood stem cells into peripheral vein, open approach
		30230Y2	Transfusion of allogeneic related hematopoietic stem cells into peripheral vein, open approach
		30230Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into peripheral vein, open approach
		30230Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into peripheral vein, open approach
		30233G2	Transfusion of allogeneic related bone marrow into peripheral vein, percutaneous approach
		30233G3	Transfusion of allogeneic unrelated bone marrow into peripheral vein, percutaneous approach
		30233G4	Transfusion of allogeneic unspecified bone marrow into peripheral vein, percutaneous approach
		30233X2	Transfusion of allogeneic related cord blood stem cells into peripheral vein, percutaneous approach
		30233X3	Transfusion of allogeneic unrelated cord blood stem cells into peripheral vein, percutaneous approach
		30233X4	Transfusion of allogeneic unspecified cord blood

List of Diagnosis and Procedure Codes Used for Incyte JAKAFI™ Cost Analysis			
Group	**Code Type**	**Codes**	**Description**
			stem cells into peripheral vein, percutaneous approach
		30233Y2	Transfusion of allogeneic related hematopoietic stem cells into peripheral vein, percutaneous approach
		30233Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into peripheral vein, percutaneous approach
		30233Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into peripheral vein, percutaneous approach
		30240G2	Transfusion of allogeneic related bone marrow into central vein, open approach
		30240G3	Transfusion of allogeneic unrelated bone marrow into central vein, open approach
		30240G4	Transfusion of allogeneic unspecified bone marrow into central vein, open approach
		30240X2	Transfusion of allogeneic related cord blood stem cells into central vein, open approach
		30240X3	Transfusion of allogeneic unrelated cord blood stem cells into central vein, open approach
		30240X4	Transfusion of allogeneic unspecified cord blood stem cells into central vein, open approach
		30240Y2	Transfusion of allogeneic related hematopoietic stem cells into central vein, open approach
		30240Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into central vein, open approach
		30240Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into central vein, open approach
		30243G2	Transfusion of allogeneic related bone marrow into central vein, percutaneous approach
		30243G3	Transfusion of allogeneic unrelated bone marrow into central vein, percutaneous approach
		30243G4	Transfusion of allogeneic unspecified bone marrow into central vein, percutaneous approach
		30243X2	Transfusion of allogeneic related cord blood stem cells into central vein, percutaneous approach
		30243X3	Transfusion of allogeneic unrelated cord blood stem cells into central vein, percutaneous approach
		30243X4	Transfusion of allogeneic unspecified cord blood stem cells into central vein, percutaneous approach
		30243Y2	Transfusion of allogeneic related hematopoietic stem cells into central vein, percutaneous approach

List of Diagnosis and Procedure Codes Used for Incyte JAKAFI™ Cost Analysis			
Group	**Code Type**	**Codes**	**Description**
		30243Y3	Transfusion of allogeneic unrelated hematopoietic stem cells into central vein, percutaneous approach
		30243Y4	Transfusion of allogeneic unspecified hematopoietic stem cells into central vein, percutaneous approach

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The applicant identified a total of 210 cases mapping to MS–DRGs 014 (Allogeneic Bone Marrow Transplant), 808 (Major Hematological and Immunological Diagnoses except Sickle Cell Crisis and Coagulation Disorders with MCC), 809 (Major Hematological and Immunological Diagnoses except Sickle Cell Crisis and Coagulation Disorders with CC), and 871 (Septicemia or Severe Sepsis without MV >96 hours with MCC). The applicant indicated that, because it is difficult to determine the realistic amount of drug charges to be replaced or avoided as a result of the use of JAKAFI™, it provided two scenarios to demonstrate that JAKAFI™ meets the cost criterion. In the first scenario, the applicant removed 100 percent of pharmacy charges to conservatively estimate the charges for drugs that potentially may be replaced or avoided by the use of JAKAFI™. The applicant then standardized the charges and applied a 2-year inflation factor of 8.864 percent, which is the same inflation factor used by CMS to update the outlier threshold in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41722). (We note that this figure was revised in the FY 2019 IPPS/LTCH PPS final rule correction notice. The corrected final 2-year inflation factor is 1.08986 (83 FR 49844).) The applicant then added charges for JAKAFI™ to the inflated average case-weighted standardized charges per case. No other related charges were added to the cases.

Under the assumption of 100 percent of historical drug charges removed, the applicant calculated the inflated average case-weighted standardized charge per case to be $261,512 and the average case-weighted threshold amount to be $172,493. Based on this analysis, the applicant believed that JAKAFI™ meets the cost criterion because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount.

As noted above, the applicant also submitted a second scenario to demonstrate that JAKAFI™ meets the cost criterion. The applicant indicated that removing all charges for previous technologies as demonstrated in the first scenario is unlikely to reflect the actual case because many drugs are used in treating a diagnosis of aGVHD, especially during the initial bone marrow transplant. Therefore, the applicant also provided a sensitivity analysis where it did not remove any pharmacy charges or any other historical charges, which it indicated could be a more realistic assumption. Under this scenario, the final average case-weighted standardized charge per case is $377,494, which exceeds the average case-weighted threshold amount of $172,493. The applicant maintained that JAKAFI™ also meets the cost criterion under this scenario.

We are inviting public comments on whether JAKAFI™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that JAKAFI™ represents a substantial clinical improvement because: (1) The technology offers a treatment option for a patient population previously ineligible for treatments because JAKAFI™ (if approved) would be the first FDA-approved treatment option for patients who have been diagnosed with GVHD who have had an inadequate response to corticosteroids; and (2) use of the technology significantly improves clinical outcomes in patients with steroid-refractory aGVHD, which the applicant asserts is supported by the results from REACH1, a prospective, open-label, single-cohort Phase II study of the use of JAKAFI™, in combination with corticosteroids, for the treatment of Grade II to IV steroid-refractory aGVHD.

The applicant stated that there are very few prospective studies evaluating second-line therapy for a diagnosis of steroid-refractory aGVHD, and interpretation of these studies is hampered by the heterogeneity of the patient population, small sample sizes, and lack of standardization in the study design (including timing of the response, different response criteria, and absence of validated endpoints). Agents that have been investigated over the last 2 decades in these studies include low-dose methotrexate, mycophenolate mofetil, extracorporeal photopheresis, IL–2R targeting (that is, basiliximab, daclizumab, denileukin, and diftitox), alemtuzumab, horse antithymocyte globulin, etanercept, infliximab, and sirolimus. The applicant stated that second-line treatments, especially those associated with suppression of T-cells, are associated with increased infection and viral reactivation (including cytomegalovirus (CMV), Epstein-Barr virus, human herpes virus 6, adenovirus, and polyoma). Numerous combination approaches (for example, antibodies directed against IL–2 receptor, mammalian target of rapamycin inhibitors, or other immunosuppressive agents) also have been studied for the treatment of steroid-refractory aGVHD, but the applicant indicated that data do not support the recommendation or exclusion of any particular regimen. The applicant also asserted that such treatment combination approaches have been associated with significant toxicities, high failure rates, and an average 6-month survival rate of 49 percent.[302] Therefore, the applicant maintains that therapeutic options are limited for patients who are refractory to corticosteroid treatment for a diagnosis of aGVHD.

The applicant asserted that the clinical benefit of the use of JAKAFI™ in patients who have been diagnosed with steroid-refractory aGVHD is supported by the results from five clinical studies, including a mixture of prospective and retrospective studies.

The first study is REACH1, a prospective, open-label, single-cohort Phase II study of the use of JAKAFI™, in combination with corticosteroids, for the treatment of Grade II to IV steroid-refractory aGVHD. REACH1 included 71 patients who had been diagnosed with steroid-refractory aGVHD. Included eligible patients were those that were 12

[302] Martin, P.J., Rizzo, J.D., Wingard, J.R., et al., ''First and second-line systemic treatment of acute graft-versus-host disease: recommendations of the American Society of Blood and Marrow Transplantation,'' *Biol Blood Marrow Transplant,* 2012, vol. 18(8), pp. 1150–1163.

years old or older, had undergone at least one allogeneic hematopoietic stem cell transplantation from any donor source and donor type and were diagnosed with Grade II to IV steroid-refractory aGVHD, and presented evidence of myeloid engraftment. The patients' median age was 58 years old (ages 18 years old to 73 years old); 66 patients were white and 36 patients were female. The majority of patients had peripheral blood stem cells as the graft source (57 patients or 80.3 percent). The starting dose of JAKAFI™ was 5 mg twice daily (BID). The dose could be increased to 10 mg BID after 3 days, if hematologic parameters were stable and in the absence of any treatment-related toxicities. Methylprednisolone (or prednisone equivalent) was administered at a starting dose of 2 mg/kg/day on the first day of treatment and tapered as appropriate. Patients receiving calcineurin inhibitors or other medications for GVHD prophylaxis were permitted to continue at the investigator's discretion. The primary endpoint was overall response rate (ORR) at Day 28, which the applicant indicated has been shown to be predictive of non-relapse mortality (NRM). No description of the statistical methods used in the REACH1 study was provided by the applicant.

The applicant stated that the ORR at Day 28 was achieved by 54.9 percent of patients; nearly half (48.7 percent) of the responding patients achieved a complete response (CR). The best ORR was 73.2 percent. Median time to first response for all responders was 7 days. Median duration of response was 345 days for both Day 28 responders (lower limit, 159 days) and for other responders (lower limit, 106 days). Event-free probability estimates for Day 28 responders at 3 and 6 months were 81.6 percent and 65.2 percent, respectively. Among all patients, median (95 percent CI) overall survival was 232.0 (93.0–not evaluable) days. Mean survival rates for the 39 responders at Day 28 were 73.2 percent at 6 months, 69.9 percent at 9 months, and 66.2 percent at 12 months with non-relapsed mortality of 21.2 percent at 6 months, 24.5 percent at 9 months, and 28.2 percent at 12 months. Mean survival rates for the 13 other responders were 35.9 percent at 6 and 9 months and were not evaluable at 12 months with non-relapsed mortality at 64.1 percent at 6 and 9 months and not evaluable at 12 months. Mean survival rates for non-responders were 15.8 percent at 6 months and 10.5 percent at 9 months and 12 months with non-relapsed mortality at 78.9 percent at 6 months and 84.2 percent at 9 and 12 months. Most patients (55.8 percent) had a greater than or equal to 50 percent reduction from baseline in corticosteroid dose.

The applicant stated that the additional use of JAKAFI™ to corticosteroid-based treatment did not result in unexpected toxicities or exacerbation of known toxicities related to high-dose corticosteroids or aGVHD. Cytopenias were among the most common treatment-emergent adverse events. The applicant indicated that JAKAFI™ was well tolerated, and the adverse event profile was consistent with the observed safety profiles of the use of JAKAFI™ and that of patients who had been diagnosed with steroid-refractory aGVHD. The most common treatment emergent adverse events in the REACH1 study were anemia (64.8 percent), hypokalemia (49.3 percent), peripheral edema (45.1 percent), decreased platelet count (45.1 percent), decreased neutrophil count (39.4 percent), muscular weakness (33.8 percent), dyspnea (32.4 percent), hypomagnesaemia (32.4 percent), hypocalcemia (31 percent), and nausea (31 percent). The most common treatment emergent infections were sepsis (12.7 percent) and bacteremia (9.9 percent).

All patients who had a CMV event (n=14) had a positive CMV donor or recipient serostatus or both at baseline. No deaths were attributed to CMV events. The applicant asserted that the results of the prospective REACH1 study demonstrate the potential of the use of JAKAFI™ to meaningfully improve the outcomes of allo-HSCT patients who develop steroid-refractory aGVHD, and further underscore the promise of JAK inhibition to advance the treatment of this potentially-devastating condition. Longer term follow-up analyses from REACH1 are expected to yield additional insights into the long-term efficacy and safety profile of the use of JAKAFI™ in this patient population.

In a second prospective, open-label study, 14 patients who had been diagnosed with acute or chronic GVHD that were refractory to corticosteroids and at least 2 other lines of treatment were treated with JAKAFI™ at a dose of 5 mg twice a day and increased to 10 mg twice a day. Of the 14 patients, 13 responded with respect to clinical GVHD symptoms and serum levels of pro-inflammatory cytokines. Three patients with histologically-proven acute skin or intestinal GVHD Grade I, achieved a CR. One non-responder discontinued use of JAKAFI™ after 1 week because of lack of efficacy. In all other patients, corticosteroids could be reduced after a median treatment period of 1.5 weeks. CMV reactivation was observed in 4 out of the 14 patients, and they responded well to antiviral therapy. Until last follow-up, no patient experienced a relapse of GVHD.

The applicant asserted that the efficacy and safety of the use of JAKAFI™ for the treatment of steroid-refractory aGVHD is further supported by the results from a third study, a retrospective, multi-center study of 95 patients who received JAKAFI™ as salvage therapy for corticosteroid-refractory GVHD. In the 54 patients who had been diagnosed with aGVHD, the median number of GVHD therapies received was 3. The (best) ORR was 81.5 percent. A CR and partial response (PR) was achieved in 46.3 percent and 35.2 percent of patients, respectively. Median time to response was 1.5 weeks (range 1 to 11 weeks). Cytopenias and cytomegalovirus reactivation were seen in 55.5 percent (Grade III or IV) and 33.3 percent of patients who had been diagnosed with aGVHD, respectively. Of those patients responding to treatment with JAKAFI™, with either CR or PR (n=44), the rate of GVHD-relapse was 6.8 percent (3/44). The 6-month-survival was 79 percent (67.3 percent to 90.7 percent, 95 percent CI). The median follow-up time was 26.5 weeks (range 3 to 106 weeks). Underlying malignancy relapse occurred in 9.2 percent of patients who had been diagnosed with aGVHD.

A fourth retrospective study evaluated data from the same 95 patients in 19 stem cell transplant centers in Europe and the United States. For long-term results, CR was defined as the absence of any symptoms related to GVHD; PR was defined as the improvement of greater than or equal to 1 in stage severity in one organ, without deterioration in any other organ. A response had to last for at least or more than 3 weeks. Of the 54 patients who had been diagnosed with aGVHD, the 1-year overall survival (OS) rate was 62.4 percent (CI: 49.4 percent to 75.4 percent). The estimated median OS (50 percent death) was 18 months for aGVHD patients. The median duration of JAKAFI™ treatment was 5 months. At follow-up, 22/54 (41 percent) of the patients had an ongoing response and were free of any immunosuppression. Cytopenias (any grade) and CMV-reactivation were observed during JAKAFI™-treatment (30/54, 55.6 percent and 18/54, 33.3 percent, respectively).

A fifth retrospective study evaluated 79 patients who received treatment

using JAKAFI™ for refractory GVHD at 13 centers in Spain. Twenty-two patients had a diagnosis of aGVHD (Grades II to IV) and received a median of 2 previous GVHD therapies (range, 1 to 5 therapies). The median daily dose of JAKAFI™ was 20 mg. The overall response rate was 68.2 percent, which was obtained after a median of 2 weeks of treatment, and 18.2 percent (4/22) of the patients reached CR. Overall, steroid doses were tapered in 72 percent of the patients who had been diagnosed with aGVHD. Cytomegalovirus reactivation was reported in 54.5 percent of the patients who had been diagnosed with aGVHD. Overall, 26 patients (32.9 percent) discontinued treatment using JAKAFI™ due to: Lack of response (14), cytopenias (3 patients had thrombocytopenia, 3 had anemia, and 3 had both); infections (1 patient); other causes (2 patients). Ten deaths occurred in patients who had been diagnosed with aGVHD.

We note the following concerns with respect to whether JAKAFI™ represents a substantial clinical improvement. First, while the applicant has submitted data from several clinical studies to support the efficacy of the use of JAKAFI™ in treatment of patients who have been diagnosed with steroid-resistant aGVHD, including an overall response rate at Day 28 for 54.9 percent of the patients enrolled in one study, with nearly half of the responding patients achieving CR, the applicant has not provided any data directly comparing the use of JAKAFI™ to any second-line treatments. As noted previously, a number of different agents can be used for second-line treatment as described by recommendations from the American Society of Blood and Marrow Transplantation (ASBMT).[303] Numerous combination approaches have been investigated for second-line therapy for diagnoses of steroid-refractory aGVHD in allo-HSCT patients. These studied agents include methotrexate, mycophenolate mofetil, extracorporeal photopheresis, IL–2R targeting agents (basiliximab, daclizumab, denileukin, and diftitox), alemtuzumab, horse antithymocyte globulin, etancercept, infliximab, and sirolimus. Recommendations from professional societies for the treatment of diagnoses of aGVHD describe the lack of data demonstrating superior efficacy of any single agent as second-line therapy for patients who have been diagnosed with steroid-resistant aGVHD and, therefore, suggest that choice of second-line treatment be guided by clinical considerations.[304] Because the applicant has not provided any data directly comparing the use of JAKAFI™ to any other second-line treatments (for example, current standard-of-care), it may make it difficult to directly assess whether the use of JAKAFI™ provides a substantial clinical improvement compared to these existing therapies.

Second, we have concerns regarding the methodologic approach of the studies submitted by the applicant in support of its assertions regarding substantial clinical improvement. While two of the clinical studies provided by the applicant are prospective in nature, the other three clinical studies provided in support of the application are retrospective studies and, therefore, provide a weaker basis of evidence for making conclusions of the causative effects of the drug compared to prospective studies. Additionally, no blinding or randomization occurred to minimize potential biases from the lack of a control group, and no Phase III study data were submitted by the applicant, to assist in our evaluation of substantial clinical improvement. Although we acknowledge that the patient population that would be eligible for treatment involving JAKAFI™ under its proposed indication is likely relatively small because it is a subset of the patient population receiving allo-HSCTs, it may be difficult to evaluate the impact of the technology on longer term outcomes, such as overall survival and durability of response based on the studies submitted because the clinical studies are based on relatively small sample sizes.

Third, given the variable amount of detail provided on the studies generally (for example, the number of patients from the United States, how many are Medicare eligible and the results for these Medicare-eligible patients, what specific first-line treatments enrolled patients received and for what duration, how CRs and PRs were defined and assessed, statistical methods and assumptions), it is more difficult to fully assess the generalizability of the applicant's assertions to the Medicare population.

Fourth, we note that several patients enrolled in each of the studies provided by the applicant had safety-related complications, including cytopenias and CMV reactivation. These complications are concerning because the target population is already immunocompromised and at risk of serious infections.

We are inviting public comments on whether JAKAFI™ meets the substantial clinical improvement criterion, including with respect to the concerns we have raised.

We did not receive any written comments in response to the New Technology Town Hall Meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for JAKAFI™ or at the New Technology Town Hall meeting.

o. Supersaturated Oxygen (SSO_2) Therapy (DownStream® System)

TherOx, Inc. submitted an application for new technology add-on payments for Supersaturated Oxygen (SSO_2) Therapy (the DownStream® System) for FY 2020. We note that the applicant previously submitted an application for new technology add-on payments for FY 2019, which was withdrawn prior to the issuance of the FY 2019 IPPS/LTCH PPS final rule. The DownStream® System is an adjunctive therapy that creates and delivers superoxygenated arterial blood directly to reperfused areas of myocardial tissue which may be at risk after an acute myocardial infarction (AMI), or heart attack. SSO_2 Therapy's proposed indication is for patients receiving treatment for an ST-segment elevation myocardial infarction (STEMI), a type of AMI where the anterior wall infarction impacts the left ventricle (LV) and which carries a substantial risk of death and disability. Elderly patients have an elevated risk of AMI, and the vast majority of AMI occur in the Medicare population.[305] The applicant stated that the net effect of the SSO_2 Therapy is to reduce the size of the infarction and, therefore, lower the risk of heart failure and mortality, as well as improve quality of life for STEMI patients.

SSO_2 Therapy consists of three main components: The DownStream® System; the DownStream cartridge; and the SSO_2 delivery catheter. The DownStream® System and cartridge function together to create an oxygen-enriched saline solution called SSO_2 solution from hospital-supplied oxygen and physiologic saline. A small amount of

[303] Martin, P.J., Rizzo, J.D., Wingard, J.R., et al., ''First and second-line systemic treatment of acute graft-versus-host disease: recommendations of the American Society of Blood and Marrow Transplantation,'' *Biol Blood Marrow Transplant,* 2012, vol. 18(8), pp. 1150–1163.

[304] Martin, P.J., Rizzo, J.D., Wingard, J.R., et al., ''First and second-line systemic treatment of acute graft-versus-host disease: recommendations of the American Society of Blood and Marrow Transplantation,'' *Biol Blood Marrow Transplant,* 2012, vol. 18(8), pp. 1150–1163.

[305] Wang, Y., Lichtman, J.H., Dharmarajan, K., Masoudi, F.A., Ross, J.S., Dodson, J.A., Chen, J., Spertus, J.A., Chaudhry, S.I., Nallamothu, B.K., Krumholz, H.M., 2014, ''National trends in stroke after acute myocardial infarction among Medicare patients in the United States: 1999 to 2010,'' *American Heart Journal,* vol. 169(1), pp. 78–85.e4.

the patient's blood is then mixed with the SSO_2 solution, producing oxygen-enriched hyperoxemic blood, which is delivered to the left main coronary artery (LMCA) via the delivery catheter at a flow rate of 100 ml/min. The duration of the SSO_2 Therapy is 60 minutes and the infusion is performed in the catheterization laboratory. The oxygen partial pressure (pO_2) of the infusion is elevated to ~1,000 mmHg, therefore providing oxygen locally to the myocardium at a hyperbaric level for 1 hour. After the 60-minute SSO_2 infusion is complete, the cartridge is unhooked from the patient and discarded per standard practice. Coronary angiography is performed as a final step before removing the delivery catheter and transferring the patient to the intensive care unit (ICU).

The applicant for the SSO_2 Therapy received premarket approval from the FDA on April 4, 2019. The applicant stated that use of the SSO_2 Therapy can be identified by the ICD–10–PCS procedure codes 5A0512C (Extracorporeal supersaturated oxygenation, intermittent) and 5A0522C (Extracorporeal supersaturated oxygenation, continuous).

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. The applicant identified three treatment options currently available to restore coronary artery blood flow in AMI patients. These options are fibronolytic therapy (plasminogen activators) with or without glycoprotein IIb/IIIa inhibitors, percutaneous coronary intervention (PCI) with or without stent placement, and coronary artery bypass graft (CABG). The applicant noted that all of these therapies restore blood flow at the macrovascular level by targeting the coronary artery thrombosis that is the direct cause of the AMI. The applicant also noted that PCI with stenting is the preferred treatment for STEMI patients. The applicant asserted that SSO_2 Therapy is not substantially similar to these existing treatment options and, therefore, meets the newness criterion. Below we summarize the applicant's assertions with respect to whether the SSO_2 Therapy meets each of the three substantial similarity criteria.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that SSO_2 Therapy is a unique therapy designed to deliver localized hyperbaric oxygen equivalent to the coronary arteries immediately after administering the standard-of-care, PCI with stenting. The applicant describes SSO_2 Therapy's mechanism of action as two-fold: (1) First, the increased oxygen levels act to re-open the microcirculatory system within the infarct zone, which has experienced ischemia during the occlusion period, and (2) second, once the microcirculatory system is re-opened, the blood flow containing the additional oxygen re-starts metabolic processes within the stunned myocardium. According to the applicant, the net result is to reduce the extent of necrosis as measured by infarct size in the myocardium post-AMI and thereby improve left ventricular function, leading to improved patient outcomes. The applicant maintained that this mechanism of action is not comparable to that of any existing treatment because no other therapy has demonstrated an infarct size reduction over and above the routine delivery of PCI. As mentioned above, the applicant asserted that currently available therapies restore blood flow at the macrovascular level by targeting the coronary artery thrombosis that is the direct cause of the AMI.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant reiterated that the standard procedure for treating patients with AMI is PCI with stent placement, and that these cases are typically assigned to MS–DRG 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries/Stents), MS–DRG 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC), MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries/Stents), MS–DRG 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC), MS–DRG 250 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC), or MS–DRG 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent without MCC). The applicant maintained that because no other technologies exist that can deliver localized hyperbaric oxygen in the acute care setting, SSO_2 Therapy has no analogous MS–DRG assignment. However, we note that potential cases that may be eligible for treatment involving SSO_2 Therapy may be assigned to the same MS–DRG(s) as other cases involving PCI with stent placement also used to treat patients who have been diagnosed with AMI.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, the target patient population of SSO_2 Therapy is patients who are receiving treatment after a diagnosis of AMI and specifically ST-segment elevation myocardial infarction (STEMI) where the anterior wall infarction impacts the left ventricle (LV). The applicant acknowledged that, because SSO_2 Therapy is administered following completion of successful PCI, its target patient population includes a subset of patients with the same or similar type of disease process as patients treated with PCI with stent placement. However, the applicant also asserted that, while PCI with stenting achieves the goal of re-opening a blocked artery, SSO_2 Therapy delivers localized hyperbaric oxygen to reduce the extent of the myocardial necrosis that occurs as a consequence of experiencing AMI. Therefore, the applicant believed that SSO_2 Therapy offers a treatment option for a different type of disease than currently available treatments.

We are inviting public comments on whether the SSO_2 Therapy is substantially similar to existing technologies and whether it meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that SSO_2 Therapy meets the cost criterion. The applicant searched the FY 2017 MedPAR file for claims reporting diagnoses of anterior STEMI by ICD–10–CM diagnosis codes I21.0 (ST elevation myocardial infarction of anterior wall), I21.01 (ST elevation (STEMI) myocardial infarction involving left main coronary artery), I21.02 (ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery), or I21.09 (ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall) as a primary diagnosis, which the applicant believed would describe potential cases representing potential patients who may be eligible for treatment involving the SSO_2 Therapy. The applicant identified 11,668 cases mapping to 4 MS–DRGs, with approximately 91 percent of all potential cases mapping to MS–DRG 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries/Stents) and MS–DRG 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC). The remaining 9 percent of potential cases

mapped to MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries/Stents) and MS–DRG 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC).

The applicant determined that the average case-weighted unstandardized charge per case was $98,846. The applicant then standardized the charges. The applicant did not remove charges for the current treatment because, as discussed above, SSO_2 Therapy would be used as an adjunctive treatment option following successful PCI with stent placement. The applicant then added charges for the technology, which accounts for the use of 1 cartridge per patient, to the average charges per case. The applicant did not apply an inflation factor to the charges for the technology. The applicant also added charges related to the technology, to account for the additional supplies used in the administration of SSO_2 Therapy, as well as 70 minutes of procedure room time, including technician labor and additional blood tests. The applicant inflated the charges related to the technology. Based on the FY 2019 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case-weighted threshold amount was $96,267. In the applicant's analysis, the inflated average case-weighted standardized charge per case was $144,364. Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We are inviting public comments on whether the SSO_2 Therapy meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that SSO_2 Therapy represents a substantial clinical improvement over existing technologies because it improves clinical outcomes for STEMI patients as compared to the currently available standard-of-care treatment, PCI with stenting alone. Specifically, the applicant asserted that: (1) Infarct size reduction improves mortality outcomes; (2) infarct size reduction improves heart failure outcomes; (3) SSO_2 Therapy significantly reduces infarct size; (4) SSO_2 Therapy prevents left ventricular dilation; and (5) SSO_2 Therapy reduces death and heart failure at 1 year. The applicant highlighted the importance of the SSO_2 Therapy's mechanism of action, which treats hypoxemic damage at the microvascular or microcirculatory level. Specifically, the applicant noted that microvascular impairment in the myocardium is irreversible and leads to a greater extent of infarction. According to the applicant, the totality of the data on myocardial infarct size, ventricular remodeling, and clinical outcomes strongly supports the substantial clinical benefit of SSO_2 Therapy administration over the standard-of-care.

To support the claims that infarct size reduction improves mortality and heart failure outcomes, the applicant cited an analysis of the Collaborative Organization for RheothRx Evaluation (CORE) trial and a pooled patient-level analysis.

- The CORE trial was a prospective, randomized, double-blinded, placebo-controlled trial of Poloxamer 188, a novel therapy adjunctive to thrombolysis at the time the study was conducted.[306] The applicant sought to relate left ventricular ejection fraction (EF), end-systolic volume index (ESVI) and infarct size (IS), as measured in a single, randomized trial, to 6-month mortality after myocardial infarction treated with thrombolysis. According to the applicant, subsets of clinical centers participating in CORE also participated in one or two radionuclide sub-studies: (1) Angiography for measurement of EF and absolute, count-based LV volumes; and (2) single-photon emission computed tomographic sestamibi measurements of IS. These sub-studies were performed in 1,194 and 1,181 patients, respectively, of the 2,948 patients enrolled in the trial. Furthermore, ejection fraction, ESVI, and IS, as measured by central laboratories in these sub-studies, were tested for their association with 6-month mortality. According to the applicant, the results of the study showed that ejection fraction (n=1,137; p=0.0001), ESVI (n=945; p=0.055) and IS (n=1,164; p=0.03) were all associated with 6-month mortality, therefore, demonstrating the relationship between these endpoints and mortality.[307]
- The pooled patient-level analysis was performed from 10 randomized, controlled trials (with a total of 2,632 patients) that used primary PCI with stenting.[308] The analysis assessed infarct size within 1 month after randomization by either cardiac magnetic resonance (CMR) imaging or technetium-99m sestamibi single-photon emission computed tomography (SPECT), with clinical follow-up for 6 months. Infarct size was assessed by CMR in 1,889 patients (71.8 percent of patients) and by SPECT in 743 patients (28.2 percent of patients) including both inferior wall and more severe anterior wall STEMI patients. According to the applicant, median infarct size (or percent of left ventricular myocardial mass) was 17.9 percent and median duration of clinical follow-up was 352 days. The Kaplan-Meier estimated 1-year rates of all-cause mortality, re-infarction, and HF hospitalization were 2.2 percent, 2.5 percent, and 2.6 percent, respectively. The applicant noted that a strong graded response was present between infarct size (per 5 percent increase) and the 2 outcome measures of subsequent mortality (Cox-adjusted hazard ratio: 1.19 [95 percent confidence interval: 1.18 to 1.20]; p<0.0001) and hospitalization for heart failure (adjusted hazard ratio: 1.20 [95 percent confidence interval: 1.19 to 1.21]; p<0.0001), independent of other baseline factors.[309] The applicant concluded from this study that infarct size, as measured by CMR or technetium-99m sestamibi SPECT within 1 month after primary PCI, is strongly associated with all-cause mortality and hospitalization for heart failure within 1 year.

Next, to support the claim that SSO_2 Therapy significantly reduces infarct size, the applicant cited the AMIHOT I and II studies.

- The AMIHOT I clinical trial was designed as a prospective, randomized evaluation of patients who had been diagnosed with AMI, including both anterior and inferior patients, and received treatment with either PCI with stenting alone or with SSO_2 Therapy as an adjunct to successful PCI within 24 hours of symptom onset.[310] The study included 269 randomized patients and 3 co-primary endpoints: Infarction size reduction, regional wall motion score improvement at 3 months, and reduction in ST segment elevation. The study was designed to demonstrate superiority of the SSO_2 Therapy group as compared to the control group for each of these endpoints, as well as to demonstrate non-inferiority of the SSO_2 Therapy group with respect to 30-day Major Adverse Cardiac Event (MACE). The applicant stated that results for the control versus SSO_2 Therapy group

[306] Burns, R.J., Gibbons, R.J., Yi, Q., et al., ''The relationships of left ventricular ejection fraction, end-systolic volume index and infarct size to six-month mortality after hospital discharge following myocardial infarction treated by thrombolysis,'' *J Am Coll Cardiol,* 2002, vol. 39, pp. 30–6.

[307] Ibid.

[308] Stone, G.W., Selker, H.P., Thiele, H., et al., ''Relationship between infarct size and outcomes following primary PCI,'' *J Am Coll Cardiol,* 2016, vol. 67(14), pp. 1674–83.

[309] Ibid.

[310] O'Neill, W.W., Martin, J.L., Dixon, S.R., et al., ''Acute Myocardial Infarction with Hyperoxemic Therapy (AMIHOT), *J Am Coll Cardiol,* 2007, vol. 50(5), pp. 397–405.

comparisons for the three co-primary effectiveness endpoints demonstrated a nominal improvement in the test group, although this nominal improvement did not achieve clinical and statistical significance in the entire population. The applicant further stated that a pre-specified analysis of the SSO_2 Therapy patients who were revascularized within 6 hours of AMI symptom onset and who had anterior wall infarction showed a marked improvement in all 3 co-primary endpoints as compared to the control group.[311] Key safety data revealed no statistically significant differences in the composite primary endpoint of 1-month (30 days) MACE rates between the SSO_2 Therapy and control groups. MACE includes the combined incidence of death, re-infarction, target vessel revascularization, and stroke. In total, 9/134 (6.7 percent) of the patients in the SSO_2 Therapy group and 7/135 (5.2 percent) of the patients in the control group experienced 30-day MACE (p=0.62).[312]

• The AMIHOT II trial randomized 301 patients who had been diagnosed with and receiving treatment for anterior AMI with either PCI plus the SSO_2 Therapy or PCI alone.[313] The AMIHOT II trial had a Bayesian statistical design that allows for the informed borrowing of data from the previously completed AMIHOT I trial. The primary efficacy endpoint of the study required proving superiority of the infarct size reduction, as assessed by Tc-99m Sestamibi SPECT imaging at 14 days post PCI/stenting, with the use of SSO_2 Therapy as compared to patients who were receiving treatment involving PCI with stenting alone. The primary safety endpoint for the AMIHOT II trial required a determination of non-inferiority in the 30-day MACE rate, comparing the SSO_2 Therapy group with the control group, within a safety delta of 6.0 percent.[314] Endpoint evaluation was performed using a Bayesian hierarchical model that evaluated the AMIHOT II result conditionally in consideration of the AMIHOT I 30-day MACE data. According to the applicant, the results of the AMIHOT II trial showed that the use of SSO_2 therapy, together with PCI and stenting, demonstrated a relative reduction of 26 percent in the left ventricular infarct size and absolute reduction of 6.5 percent compared to PCI and stenting alone.[315]

Next, to support the claim that SSO_2 Therapy prevents left ventricular dilation, the applicant cited the Leiden study, which represents a single-center, sub-study of AMIHOT I patients treated at Leiden University in the Netherlands. The study describes outcomes of randomized selective treatment with intracoronary aqueous oxygen (AO), the therapy delivered by SSO_2 Therapy, versus standard care in patients who had acute anterior wall myocardial infarction within 6 hours of onset. Of the 50 patients in the sub-study, 24 received treatment using adjunctive AO and 26 were treated according to standard care after PCI, with no significant differences in baseline characteristics between groups. LV volumes and function were assessed by contrast echocardiography at baseline and 1 month. According to the applicant, the results demonstrated that treatment with aqueous oxygen prevents LV remodeling, showing a reduction in LV volumes (3 percent decrease in LV end-diastolic volume and 11 percent decrease in LV end-systolic volume) at 1 month as compared to baseline in AO-treated patients, as compared to increasing LV volumes (14 percent increase in LV end diastolic volume and 18 percent increase in LV end-systolic volume) at 1 month in control patients.[316] The results also show that treatment using AO preserves LV ejection fraction at 1 month, with AO-treated patients experiencing a 10 percent increase in LV ejection fraction as compared to a 2 percent decrease in LV ejection fraction among patients in the control group.[317]

Finally, to support the claim that SSO_2 Therapy reduces death and heart failure at 1 year, the applicant submitted the results from the IC–HOT clinical trial, which was designed to confirm the safety and efficacy of the use of the SSO_2 Therapy in those individuals presenting with a diagnosis of anterior AMI who have undergone successful PCI with stenting of the proximal and/or mid left anterior descending artery within 6 hours of experiencing AMI symptoms. It is an IDE, nonrandomized, single arm study. The study primarily focused on safety, utilizing a composite endpoint of 30-day Net Adverse Clinical Events (NACE). A maximum observed event rate of 10.7 percent was established based on a contemporary PCI trial of comparable patients who had been diagnosed with anterior wall STEMI. The results of the IC–HOT trial exhibited a 7.1 percent observed NACE rate, meeting the study endpoint. Notably, no 30-day mortalities were observed, and the type and frequency of 30-day adverse events occurred at similar or lower rates than in contemporary STEMI studies of PCI-treated patients who had been diagnosed with anterior AMI.[318] Furthermore, according to the applicant, the results of the IC–HOT study supported the conclusions of effectiveness established in AMIHOT II with a measured 30-day median infarct size = 19.4 percent (as compared to the AMIHOT II SSO_2 Therapy group infarct size = 20.0 percent).[319] The applicant stated that notable measures include 4-day microvascular obstruction (MVO), which has been shown to be an independent predictor of outcomes, 4-day and 30-day left ventricular end diastolic and end systolic volumes, and 30-day infarct size.[320] The applicant also stated that the IC–HOT study results exhibited a favorable MVO as compared to contemporary trial data, and decreasing left ventricular volumes at 30 days, compared to contemporary PCI populations that exhibit increasing left ventricular size.[321] The applicant asserted that the IC–HOT clinical trial data continue to demonstrate the substantial clinical benefit of the use of SSO_2 Therapy as compared to the standard-of-care, PCI with stenting alone.

The applicant also performed controlled studies in both porcine and canine AMI models to determine the safety, effectiveness, and mechanism of action of the SSO_2 Therapy.[322] [323] According to the applicant, the key summary points from these animal studies are:

• SSO_2 Therapy administration post-AMI acutely improves heart function as measured by left ventricular ejection fraction (LVEF) and regional wall

[311] Ibid.

[312] Ibid.

[313] Stone, G.W., Martin, J.L., de Boer, M.J., et al., ''Effect of Supersaturated Oxygen Delivery on Infarct Size after Percutaneous Coronary Intervention in Acute Myocardial Infarction,'' *Circ Cardiovasc Intervent,* 2009, vol. 2, pp. 366–75.

[314] Ibid.

[315] Ibid.

[316] Warda, H.M., Bax, J.J., Bosch, J.G., et al., ''Effect of intracoronary aqueous oxygen on left ventricular remodeling after anterior wall ST-elevation acute myocardial infarction,'' *Am J Cardiol,* 2005, vol. 96(1), pp. 22–4.

[317] Ibid.

[318] David, SW, Khan, Z.A., Patel, N.C., et al., ''Evaluation of intracoronary hyperoxemic oxygen therapy in acute anterior myocardial infarction: The IC–HOT study,'' *Catheter Cardiovasc Interv,* 2018, pp. 1–9.

[319] Ibid.

[320] Ibid.

[321] Ibid.

[322] Spears, J.R., Henney, C., Prcevski, P., et al., ''Aqueous Oxygen Hyperbaric Reperfusion in a Porcine Model of Myocardial Infarction,'' *J Invasive Cardiol,* 2002, vol. 14(4), pp. 160–6.

[323] Spears, J.R., Prcevski, P., Xu, R., et al., ''Aqueous Oxygen Attenuation of Reperfusion Microvascular Ischemia in a Canine Model of Myocardial Infarction,'' *ASAIO J,* 2003, vol. 49(6), pp. 716–20.

motion as compared with non-treated control subjects.

- SSO_2 Therapy administration post-AMI results in tissue salvage, as determined by post-sacrifice histological measurements of the infarct size. Control animals exhibit larger infarcts than the SSO_2-treated animals.
- SSO_2 Therapy has been shown to be non-toxic to the coronary arteries, myocardium, and end organs in randomized, controlled swine studies with or without induced acute myocardial infarction.
- SSO_2 Therapy administration post-AMI has exhibited regional myocardial blood flow improvement in treated animals as compared to controls.
- A significant reduction in myeloperoxidase (MPO) levels in the SSO_2-treated animals versus controls, which indicate improvement in underlying myocardial hypoxia.
- Transmission electron microscopy (TEM) photographs showing amelioration of endothelial cell edema and restoration of capillary patency in ischemic zone cross-sectional histological examination of the SSO_2-treated animals, while non-treated controls exhibit significant edema and vessel constriction at the microvascular level.

We have the following concerns regarding whether the technology meets the substantial clinical improvement criterion. We note that the standard-of-care for STEMI has evolved since the AMIHOT I and AMIHOT II studies were conducted, such that it is unclear whether use of SSO_2 Therapy would demonstrate the same clinical improvement as compared to the current standard-of-care. We also note that the AMIHOT II study used SPECT infarct size data 14 days post-MI for efficacy and MACE events (including death, re-infarction, revascularization, and stroke) by 30 days post-MI for safety. We are concerned that there is no long-term data to demonstrate the validity of these statistics, and that infarct size has not been completely validated as a surrogate marker for the combination of PCI plus SSO_2. With respect to the IC–HOT study, we are concerned that the lack of a control may limit the interpretation of the data. We also are concerned that the safety data (death, re-infarction, re-vascularization, stent thrombosis, severe heart failure, and bleeding) for the IC–HOT study were limited to the 30 days post-MI, with no long-term data being available.

We are inviting public comments on whether the SSO_2 Therapy meets the substantial clinical improvement criterion, including with respect to whether the results of the AMIHOT I and AMIHOT II studies remain valid given the advancements in STEMI care since these trials were conducted, and the availability of long-term data to validate the efficacy and safety data of the AMIHOT II and IC–HOT studies.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the SSO_2 Therapy or at the New Technology Town Hall meeting.

p. T2Bacteria® Panel (T2 Bacteria Test Panel)

T2 Biosystems, Inc. submitted an application for new technology add-on payments for the T2 Bacteria Test Panel (T2Bacteria® Panel) for FY 2020. According to the applicant, the T2Bacteria® Panel is indicated as an aid in the diagnosis of bacteremia, bacterial presence in the blood which is a precursor for sepsis. It is a multiplex diagnostic panel that detects five major bacterial pathogens (*Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Staphylococcus aureus*) associated with sepsis. According to the applicant, the T2Bacteria® Panel is capable of detecting bacterial pathogens directly in whole blood more rapidly and with greater sensitivity as compared to the current standard-of-care, blood culture. The applicant noted that the T2Bacteria® Panel's major detected species are five of the most common and virulent sepsis-causing organisms.[324] [325] The applicant asserted that, by enabling the rapid administration of species-specific antimicrobial therapies, the T2Bacteria® Panel helps to reduce patients' hospital lengths-of-stay and substantially improves clinical outcomes. Furthermore, the applicant asserted that the T2Bacteria® Panel helps to reduce the overuse of ineffective or unnecessary antimicrobial therapy, reducing patient side effects, lowering hospital costs, and potentially counteracting the growing resistance to antimicrobial therapy.

The applicant stated that the T2Bacteria® Panel runs on the T2Dx Instrument, which is a bench-top diagnostic instrument that utilizes developments in magnetic resonance and nanotechnology to detect pathogens directly in whole blood, plasma, serum, saliva, sputum and urine at limits of detection as low as one colony forming unit per milliliter. The applicant explained that the T2Dx breaks down red blood cells, concentrates microbial cells and cellular debris, amplifies DNA using a thermostable polymerase and target-specific primers, and detects amplified product by amplicon-induced agglomeration of supermagnetic particles and T2MR measurement.[326] To perform a diagnostic test, the patient's sample tube is snapped onto the disposable test cartridge, which is pre-loaded with all necessary reagents. The cartridge is then inserted into the T2Dx, which automatically processes the sample and then delivers a diagnostic test result. The applicant asserted that each test panel is comprised of a test cartridge and a reagent tray and that each are required to run the T2Bacteria® Test Panel.

As stated above, the current standard-of-care for identifying bacterial bloodstream infections that cause sepsis is a blood culture. The applicant explained that blood culture diagnostics have many limitations, beginning with a series of time and labor intensive analyses. According to the applicant, completing a blood culture requires typically 20 mLs or more of a patient's blood, which is obtained in two 10 mL draws and placed into two blood culture bottles containing nutrients formulated to grow bacteria. The applicant explained that before the blood culture indicates if a patient is infected, pathogens typically must reach a concentration of 1,000,000 to 100,000,000 CFU/mL in the blood specimen. This growth process typically takes 1 to 6 or more days because the pathogen's initial concentration in the blood specimen is often less than 10 CFU/mL. The applicant stated that a typical blood culture provides a result in a 2 to 4 day timeframe for species ID and yields 50 to 65 percent clinical sensitivity.[327] [328] According to the applicant, a recent retrospective analysis of 13 U.S. hospitals and over

[324] Boucher, H., Talbot, G., Bradley, J., Edwards, J., Gilbert, D., Rice, L., Bartlett, J., ''Bad Bugs, No Drugs: No ESKAPE! An update from the infectious disease society of America,'' *Clinical Infectious Diseases,* 2009, vol. 48, pp. 1–12, doi:10.1086/595011.

[325] Rice, L., ''Federal Funding for the Study of Antimicrobial Resistance in Nosocomial Pathogens: No ESKAPE,'' *Journal of Infectious Diseases,* 2008, vol. 197, pp. 1079–1081, doi:10.1086/533452.

[326] Clancy, C., & Nguyen, H., ''T2 magnetic resonance for the diagnosis of bloodstream infections: charting a path forward,'' *Journal of Antimicrobial Chemotherapy,* 2018, vol. 73(4), pp. iv2–iv5, doi:10.1093/jac/dky050.

[327] Clancy, C., & Nguyen, M. H., ''Finding the ''Missing 50%'' of Invasive Candidiasis: How nonculture Diagnostics will improve understanding of disease spectrum and transform patient care,'' *Clinical Infectious Diseases,* 2013, vol. 56(9), pp. 1284–1292, doi:10.1093/cid/cit006.

[328] Cockerill, F., Wilson, J., Vetter, E., Goodman, K., Torgerson, C., Harmsen, W., Wilson, W., ''Optimal Testing Parameters for Blood Cultures,'' *Clinical Infectious Diseases,* 2004, vol. 38, pp. 1724–1730.

150,000 cultures found a median blood culture time for species ID of 43 hours.[329]

According to the applicant, blood cultures provide results at multiple stages. A negative test result requires a minimum of 5 days for blood cultures. A positive blood culture typically means that some pathogen is present, but additional steps must be performed to identify the specific pathogen and provide targeted therapy. The applicant submitted data stating that during the T2Bacteria® Panel's pivotal study, blood cultures took an average of 63.2 hours (off T2Bacteria® Panel) and 38.5 hours (on T2Bacteria® Panel) to obtain positive results and 96.0 hours (off T2Bacteria® Panel) and 71.7 hours (on T2Bacteria® Panel) to achieve species identification.[330] The applicant stated that, given this length of time to species identification, the first therapy for a patient at risk of sepsis is often broad-spectrum antibiotics, which treats some, but not all bacteria types. In addition, the applicant indicated that the time to species identification in blood culture diagnostics causes delays in administration of species-specific targeted therapies, increasing hospital lengths-of-stay and risk of death.

With respect to the newness criterion, the applicant filed a section 510(k) premarket notification with the FDA on September 8, 2017 for the T2Bacteria® Panel. According to the applicant, the T2Bacteria® Panel received FDA 510(k) clearance on May 24, 2018, based on a determination of substantial equivalence to a legally marketed predicate device. The applicant noted that the T2Bacteria® Panel has a very broad application in the inpatient hospital setting and, as a result, potential cases available for use of the T2Bacteria® Panel may be identified by thousands of ICD–10–CM diagnosis codes. We note that the applicant has submitted a request to the ICD–10 Coordination and Maintenance Committee for approval for a unique ICD–10–PCS procedure code, effective in FY 2020, to describe procedures which use the T2Bacteria® Panel. Currently, there are no ICD–10–PCS procedure codes to uniquely identify procedures involving the use of the T2Bacteria® Panel.

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that the T2Bacteria® Panel: (1) Has a different mechanism of action when compared to the current standard-of-care for the diagnosis of bacterial pathogens directly from whole blood; and (2) is designed to achieve a different therapeutic outcome when compared to the other diagnostic test panel that is based on the same technological diagnostic platform. Specifically, the applicant asserted that the standard-of-care blood culture is a laboratory test in which blood, taken from the patient, is inoculated into bottles containing culture media and incubated over a period of time to determine whether infection-causing micro-organisms (bacteria or fungi) are present in the patient's bloodstream. In contrast, the applicant stated that the T2Bacteria® Panel relies on developments in magnetic resonance and nanotechnology to determine the presence of bacterial pathogens in a patient's blood by exploiting the physics of magnetic resonance. Furthermore, the applicant indicated that the only other product on the U.S. market that uses the same or similar mechanism of action as the T2Bacteria® Panel is the T2Candida Panel, which detects five clinically relevant species of *Candida,* a fungal pathogen known to cause sepsis. However, the applicant noted that the T2Candida Panel achieves a different therapeutic outcome than the T2Bacteria® Panel, which is the diagnostic aid in the treatment of sepsis caused by fungal infections in the blood.

With regard to the second criterion, whether the technology is assigned to the same or different MS–DRG, the applicant did not comment. However, we believe that cases involving the use of the technology would be assigned to the same MS–DRGs as cases involving the current standard-of-care laboratory blood cultures.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, the T2Bacteria® Panel would be used as a diagnostic aid in the treatment of similar diseases and patient populations as the current standard-of-care laboratory blood cultures.

We are concerned that the mechanism of action of the T2Bacteria® Test Panel may be similar to the mechanism of action used by the current standard-of-care laboratory blood cultures or other available diagnostic tests. While the applicant states that the technology has a different mechanism of action because its differs from the standard-of-care, blood cultures, we note that like other available diagnostic tests, the T2Bacteria® Test Panel uses DNA to identify bacterial species. Similarly, in order to obtain species identification from the current standard-of-care, blood cultures, a DNA test is also required. Therefore, we are concerned with the similarity of this mechanism of action. We are inviting public comments on whether the T2Bacteria® Test Panel is substantially similar to the standard-of-care laboratory blood cultures or other diagnostic tests and whether this technology meets the newness criterion.

With regard to the cost criterion, the applicant provided the following analysis. To identify the MS–DRGs to which potential cases available for use of the T2Bacteria® Panel would most likely map, a selection of ICD–10–CM diagnosis codes associated with the clinical presence of the on-panel sepsis-causing bacteria for which the T2Bacteria® Test Panel tests was identified.[331] [332] [333] [334] [335] The applicant asserted that the T2Bacteria® Test Panel can identify three Gram-negative blood

[329] Tabak, Y., Vankeepuram, L., Ye, G., Jeffers, K., Gupta, V., & Murray, P., ''Blood Culture Turanaround Time in US Acute Care Hospitals and Implications for Laboratory Process Optimization,'' *Journal of Clinical Microbiology,* August 2018, pp. 1–15.

[330] T2 Biosystems, Inc., ''T2Bacteria® Panel for use on the T2Dx® Instrument, 510(k) summary,'' Lexington, 2018.

[331] Calderwood, S., ''Clinical manifestations, diagnosis and treatment of enterohemorrhagic Escherichia coli (EHEC) infection,'' September 2017. Available at: *https://www.uptodate.com/contents/clinical-manifestations-diagnosis-and-treatment-of-enterohemorrhagic-escherichia-coli-ehec-infection.*

[332] Yu, W.L., & Chuang, Y.C., ''Clinical features, diagnosis, and treatment of Klebsiella pneumoniae infection,'' May 18, 2017. Available at: *https://www.uptodate.com/contents/clinical-features-diagnosis-and-treatment-of-klebsiella-pneumoniae-infection?search=Klebsiella%20pneumoniae&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.*

[333] Kanj, S., & Sexton, D., ''Epidemiology, microbiology, and pathogenesis of Pseudomonas aeruginosa infection,'' October 9, 2018. Available at: *https://www.uptodate.com/contents/epidemiology-microbiology-and-pathogenesis-of-pseudomonas-aeruginosa-infection?search=Pseudomonas%20aeruginosa&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2.*

[334] Holland, T., & Fowler, V., ''Clinical manifestations of Staphylococcus aureus infection in adults,'' September 22, 2017. Available at: *https://www.uptodate.com/contents/clinical-manifestations-of-staphylococcus-aureus-infection-in-adults?search=Staphylococcus%20aureus&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3.*

[335] Murray, B., ''Microbiology of enterococci,'' August 31, 2017. Available at: *https://www.uptodate.com/contents/microbiology-of-enterococci?search=Enterococcus%20faecium&source=search_result&selectedTitle=2~21&usage_type=default&display_rank=2.*

stream infections (*Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*) and two Gram-positive bloodstream infection species (*Staphylococcus aureus, and Enterococcus faecium*). A total of 67 ICD–10–CM diagnosis codes were identified and segmented by two categories, infections (39 codes) and sepsis (28 codes). The applicant asserted that the former category represents potential cases available to be diagnosed by the T2Bacteria® Panel for patients who are at risk for sepsis and the latter represents potential cases available for use of the T2Bacteria® Panel for patients who have been diagnosed with a confirmed sepsis. The applicant stated that distinguishing between the two was necessary due to the varying costs associated with the treatment of patients at risk for sepsis versus confirmed cases of sepsis.

After the identification of the 39 infection and 28 sepsis diagnosis codes, both selections were refined by the applicant with the removal of cases identified by a total of 15 codes that represent pathogens not within the spectrum of blood infections that the T2Bacteria® Panel has been tested with and/or has been confirmed to detect. From the infection diagnosis codes, cases identified by two ICD–10–CM diagnosis codes: A021 (Salmonella sepsis); and A227 (Anthrax sepsis) were removed. From the sepsis diagnosis codes, cases identified by 13 diagnosis codes were removed: A021 (Salmonella sepsis); A227 (Anthrax sepsis); A400 (Sepsis due to streptococcus, group A); A401 (Sepsis due to streptococcus, group B); A403 (Sepsis due to streptococcus pneumonia); A408 (Other streptococcal sepsis); A409 (Streptococcal sepsis, unspecified); A413 (Sepsis due to hemophilus influenza); A414 (Sepsis due to anaerobes); A4153 (Sepsis due to serratia); A427 (Actinomycotic sepsis); A5486 (Gonococcal sepsis); and B377 (Candidal sepsis). The remaining infection and sepsis diagnosis codes were then used to query the FY 2017 MedPAR database to identify inpatient discharges reporting these diagnosis codes under the primary and secondary position.

According to the applicant, the resulting sets of MS–DRGs from both diagnosis code selection queries had visible commonalities when looking at only the MS–DRGs that contained potential cases which represented at least 1 percent of the discharge volume for the specific diagnoses. According to the applicant, due to the high volume of cases pulled and visible trends, provider-specific discharges at the MS–DRG level with fewer than 11 discharges were omitted from the analysis. In reconciling the list of MS–DRGs containing potential cases identified for the specific infection and sepsis codes, the applicant stated that MS–DRGs 853 (Infectious & Parasitic Diseases with O.R. Procedure with MCC), 870 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours), 871 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours with MCC) and 872 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours without MCC) contain at least 1 percent of the potential case volume under both scenarios and are the MS–DRGs to which these potential cases available for use of the T2Bacteria® Test Panel would most closely map.

The applicant provided multiple cost analysis scenarios to demonstrate that the T2Bacteria® Test Panel meets the cost criterion. Eight scenarios were provided for the Sepsis and Infection diagnosis codes, separately, using the ICD–10–CM selections and based on the following methodologies: (1) Applicable discharges for the potential cases contained in 4 MS–DRGs (853, 870, 871 and 872); (2) applicable discharges for cases inclusive of all identified MS–DRGs; (3) applicable discharges with ICU usage for potential cases contained in 4 MS–DRGs (853, 870, 871 and 872); (4) applicable discharges with ICU usage for potential cases inclusive of all identified MS–DRGs; (5) applicable discharges for cases contained in 4 MS–DRGs (853, 870, 871 and 872) with removal of 50 percent of pharmacy charges for prior technology; (6) applicable discharges for potential cases inclusive of all identified MS–DRGs with removal of 50 percent of pharmacy charges for prior technology; (7) applicable discharges with ICU usage for potential cases contained in 4 MS–DRGs (853, 870, 871 and 872) with removal of 75 percent of pharmacy charges for prior technology; and (8) applicable discharges with ICU usage for potential cases contained inclusive of all identified MS–DRGs with removal of 75 percent of pharmacy charges for prior technology.

The applicant's order of operations used for each analysis is as follows: (1) Using the 15 sepsis or 37 infection diagnosis codes; (2) using the complete set of cases or those who had an ICU stay; (3) removing pharmacy charges at 0 percent, 50 percent, or 75 percent (for ICU patients only); and (4) standardizing the charges per cases using the Impact File published with the FY 2019 IPPS/LTCH PPS final rule correction notice data file. After removing the charges for the prior technology and standardizing charges, the applicant applied an inflation factor of 1.08986, which is the 2-year inflation factor from the FY 2019 IPPS/LTCH PPS final rule correction notice (83 FR 49844) to update the charges from FY 2017 to FY 2019. The applicant then added charges for the T2Bacteria® Panel. Under each scenario, the applicant stated that the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Below we provide a table depicting the applicant's results for all 16 scenarios that the applicant indicated demonstrates that the technology meets the cost criterion.

Scenario	Final inflated average case-weighted standardized charge per case	Average case-weighted threshold amount
Sepsis Discharges for Cases Contained in 4 MS–DRGs (872, 871, 870 and 853)	$69,088	$62,699
Sepsis Discharges for Cases Inclusive of All Identified MS–DRGs	74,630	64,991
Sepsis Discharges for Cases with ICU Usage Contained in 4 MS–DRGs (872, 871, 870 and 853)	94,385	69,194
Sepsis Discharges for Cases with ICU Usage Inclusive of All Identified MS–DRGs	103,285	73,349
Sepsis Discharges for Cases Contained in 4 MS–DRGs (872, 871, 870 and 853) with Removal of 50 Percent of Pharmacy Charges for Prior Technology	63,503	62,699
Sepsis Discharges for Cases Inclusive of All Identified MS–DRGs with Removal of 50 Percent of Pharmacy Charges for Prior Technology	68,555	64,991

Scenario	Final inflated average case-weighted standardized charge per case	Average case-weighted threshold amount
Sepsis Discharges for Cases with ICU Usage Contained in 4 MS–DRGs (872, 871, 870, and 853) with Removal of 75 Percent of Pharmacy Charges for Prior Technology	82,415	69,194
Sepsis Discharges for Cases with ICU usage Inclusive of All Identified MS–DRGs with Removal of 75 Percent of Pharmacy Charges for Prior Technology	90,151	73,350
Infection Discharges for Cases Contained in 4 MS–DRGs (872, 871, 870 and 853)	69,349	60,696
Infection Discharges for Cases Inclusive of All Identified MS–DRGs	61,299	52,595
Infection Discharges for Cases with ICU Usage Contained in 4 MS–DRGs (872, 871, 870 and 853)	95,952	67,024
Infection Discharges for Cases with ICU Usage Inclusive of All Identified MS–DRGs	102,171	68,682
Infection Discharges for Cases Contained in 4 MS–DRGs (872, 871, 870 and 853) with Removal of 50 Percent of Pharmacy Charges for Prior Technology	63,744	60,696
Infection Discharges for Cases Inclusive of All Identified MS–DRGs with Removal of 50 Percent of Pharmacy Charges for Prior Technology	56,833	52,595
Infection Discharges for Cases with ICU Usage Contained in 4 MS–DRGs (872, 871, 870, and 853) with Removal of 75 Percent of Pharmacy Charges for Prior Technology	83,760	67,024
Infection Discharges for Cases with ICU Usage Inclusive of All Identified MS–DRGs with Removal of 75 Percent of Pharmacy Charges for Prior Technology	90,091	68,683

The applicant noted that, in all 16 scenarios, the average case-weighted standardized charge per case for potential cases available for aid by use of the T2Bacteria® Test Panel would exceed the average case-weighted threshold amounts in the FY 2019 IPPS/LTCH PPS final rule correction notice data file by between $803.87 and $33,488.82. Supplementary analyses were provided by the applicant, which included eight additional scenarios that combined the 15 sepsis and 37 infection diagnosis codes into one set of 52 diagnosis codes. The applicant again utilized an inflation factor of 1.08986 and followed the same methodology as the previously discussed cost analyses. The applicant again noted that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amounts in all scenarios, ranging between $1,083.67 and $32,430.57.

We are inviting public comments on whether the T2Bacteria® Panel meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the T2Bacteria® Panel represents a substantial clinical improvement over existing technologies. According to the applicant, the T2Bacteria® Panel is the only FDA-cleared diagnostic aid that has the ability to rapidly and accurately identify sepsis-causing bacteria species directly from whole blood within 3 to 5 hours, instead of the 1 to 5 days required by current standard-of-care laboratory blood cultures or other diagnostic technology. The applicant also asserted that the use of the T2Bacteria® Panel provides more rapid beneficial resolution of the disease process due to enabling faster treatment. Several studies provided by the applicant suggest that effective detection prior to therapy can lead to a reduction in hospital lengths-of-stay and likelihood of death.[336] [337] According to the applicant, in these studies for every hour reduction in time to effective therapy or species ID, the length-of-stay decreased by 2.7 hours.

The applicant stated that the T2Bacteria® pivotal trial that led to the FDA clearance enrolled 11 hospitals in the United States and 1,427 patients with a blood culture ordered as the standard-of-care, with species ID determined by MALDI–TOF or Vitek2.[338] Furthermore, due to the low prevalence of panel specific organisms, an additional 250 contrived specimens were evaluated. The T2Bacteria® Panel result was blinded to the managing staff and did not influence care. Blood samples were drawn for culture and T2Bacteria® Panel from the same line at the same time. The mean time to blood culture positivity was 51.0 ± 43.0 hours (mean ± SD) and the mean time to species ID was 83.7 ± 47.6 hours (mean ± SD). In contrast, the mean time to T2Bacteria® Panel result was 6.5 ± 1.9 hours, where a full load of 7 samples completed in 7.70 ± 1.4 hours and a single sample completed in 3.6 ± 0.02 hours. Therefore, the difference in mean time to result between blood culture and the T2Bacteria® Panel assay was 77.2 hours or 3.2 days ($p<0.001$). Compared to the matched draw blood culture and contrived samples, the overall sensitivity ranged from 81.3 percent to 100 percent and specificity ranged from 95.0 percent to 100 percent, respectively. Of the 190 positive T2Bacteria® Panel results, 35 had matching blood culture results and 155 were potentially false positive. Of these 155, 35 had a positive blood culture at another blood draw within 14 days; 30 had positive results by amplification and gene sequencing; and 23 had other positive non-blood specimens for the same organism. Sixty-three of the 190 (33 percent) positive results were not associated with evidence of infection. Later testing by the applicant confirmed that reagent contamination caused the high false positive rates specifically for *E. coli* of 1.7 percent and *P. aeruginosa* (1.7 percent) in stored blood samples. Compared to blood culture results for species identified with the T2Bacteria® Panel, the assay detected 3.2-times more positives associated with infection.

Nguyen, *et al.,* a submitted publication manuscript based on the pivotal study data used by the FDA, found that the species identification of the T2Bacteria® Panel took an average mean time of 3.61 ± 0.2 hours up to 7.70 ± 1.38 hours (mean time dependent on the number of samples loaded, 1 to 7), which was shorter than that of the standard-of-care blood culture with a

[336] Huang, A., Newton, D., Kunapuli, A., Gandhi, T., Washer, L., Isip, J., Nagel, J., ''Impact of Rapid Organism Identification via Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Combined with Antimicrobial Stewardship Team Intervention in Adult Patients with Bacteremia and Candidemia,'' *Clinical Infectious Diseases,* 2013, vol. 57(9), pp. 1237–1245.

[337] Perez, K., Olsen, R., Musick, W., Cernoch, P., Davis, J., Peterson, L., & Musser, J., ''Integrating Rapid Diagnostics and Antimicrobial Stewardship Improves Outcomes in Patients with Antibiotic-Resistant Gram-Negative Bacteremia,'' *Journal of Infection,* 2014, vol. 69(3), pp. 216–225.

[338] T2 Biosystems, Inc., ''T2Bacteria® Panel for use on the T2Dx® Instrument, 510(k) summary,'' Lexington, 2018.

mean time of 71.7 ± 39.3 hours.[339] In addition to faster species identification, the applicant asserted that the T2Bacteria® Panel identifies more infection-positive cases than blood cultures when verified by non-concurrent test results [340] or when verified with proven, probably, or possible criteria (concurrent blood culture positive results, non-concurrent blood culture results with positive culture results from another site within 21 days, and no culture match, but the T2Bacteria® Panel bacteria was a plausible cause of disease, respectively). In this study, 66 percent of patients with concomitant blood culture results and T2Bacteria® Panel positive results were not on active antibiotics at the time of the blood draw, while 24 percent of patients with probable or possible blood stream infections that were positive by T2Bacteria® Panel alone were not on effective therapy.

In another study submitted by the applicant, 137 blood cultures and T2Bacteria® Panel tests were obtained from participants in the emergency department.[341] T2Bacteria® Panel results were verified with concordant blood culture results, or when discordant with blood cultures from another location drawn within 14 days of the matched draw, or with the whole blood Sanger sequencing method. No samples generated an invalid result for the T2Bacteria® assay. The T2Bacteria® Panel identified 15 positives for which blood cultures had concordant matches for 12. The three unmatched positives were verified via other means. As compared to blood cultures, the T2Bacteria® Panel had an overall positive percent agreement of 100 percent (12/12) and a negative percent agreement of 98.4 percent (662/673). The negative percent agreement is shown to be due to blood culture results that are indeterminate, or false positive.

In the same study,[342] the T2Bacteria® Panel results relative to standard-of-care blood culture identification were classified into four impact level categories: (1) Minimal impact results have negative blood culture results with no evidence of infection for which results would have little to no impact; (2) some impact results occur for patients who have an effective therapy at the time of results, but the number of antibiotics administered could have been reduced; (3) moderate impact results are for those on effective therapy at the time of results, but were switched to species-directed therapy within 12 hours of a standard-of-care blood culture identification; and (4) direct impact results relate to those who could have been placed on effective therapy earlier based on the results of the T2Bacteria® Panel.[343] The study identified 7 ''minimal impact'' incidents, 8 ''some impact'' incidents, 4 ''moderate impact'' incidents, and 4 ''direct impact'' incidents, indicating that 16/23 (69.6 percent) of positive test results could have potentially influenced patient care.

In articles provided by the applicant which concerned separate studies, the T2Bacteria® Panel was found to have a shorter time to species identification than blood cultures.[344] [345] The study analysis by De Angelis, et al., 2018, an international, prospective observational study involving 129 patients (144 enrolled) 18 years of age and older who had a blood culture and for whom a T2Bacteria® Panel was also obtained, showed that the T2Bacteria® Panel provided a mean time to species identification and negative result of 5.5 ± 1.4 hours and 6.1 ± 1.5 hours, respectively as compared to 25.2 ± 15.2 hours and 120 ± 0.0 hours resulting from the standard-of-care blood culture method, respectively.[346] There were a total of 10 concordantly identified micro-organisms, 2 identified by standard-of-care blood culture only, and 20 detected by the T2Bacteria® Panel only. As compared to the results from the standard-of-care blood culture method, the results from the T2Bacteria® Panel had a sensitivity that ranged from 50 percent to 100 percent across the 5 detection channels, with an aggregate of 83.3 percent and a specificity that ranged from 94.8 percent to 100 percent, with an aggregate of 97.6 percent. For patients who had a matched blood culture positive (n=8) and who met the criterion of infection (n=6), a total of 36 percent (5/14) of the patients were receiving inappropriate antimicrobial therapy at the time of the T2Bacteria® Panel result. The results of this study are again discussed in another article submitted by the applicant, which states that these results may have the potential to rapidly identify the five on-panel pathogens that may include cases missed by results of the standard-of-care blood culture.[347]

The applicant further asserted that the T2Bacteria® Panel provides a decreased rate of subsequent diagnostic or therapeutic interventions. The applicant discussed the results of a meta-analysis of 70 studies, in which the proportion of patients on an inappropriate empiric therapy was 46.5 percent.[348] The applicant indicated that the results show that amongst patients with a blood culture draw, typical antibiotic administration rates range from 50 to 70 percent.[349] [350] [351] The applicant asserted that based on the results of the analysis by the Voigt, et al., manuscript, 35 percent (8/23) of the patients, receiving 3.6 ± 1.1 (mean ± SD) unique antibiotics per patient, could have potentially seen

[339] Nguyen, M.H., Clancy, C., Pasculle, A.W., Pappas, P., Alangaden, G., Pankey, G., Mylonakis, E. ''Clinical performance of the T2Bacteria panel for diagnosis bloodstream infections due to five common bacterial pathogens,'' Manuscript for submission.

[340] T2 Biosystems, Inc., ''T2Bacteria® Panel for use on the T2Dx® Instrument, 510(k) summary,'' Lexington, 2018.

[341] Voigt, C., Silbert, S., Widen, R., Marturano, J., Lowery, T., Ashcraft, D., & Pankey, G., ''The T2Bacteria assay is a sensitive and rapid detector of bacteremia that can be initiated in the emergency department and has potential to favorably influence subsequent therapy,'' *Journal of Emergency Medical Review,* pp. 1–30.

[342] Ibid.

[343] Voigt, C., Silbert, S., Widen, R., Marturano, J., Lowery, T., Ashcraft, D., & Pankey, G., ''The T2Bacteria assay is a sensitive and rapid detector of bacteremia that can be initiated in the emergency department and has potential to favorably influence subsequent therapy,'' *Journal of Emergency Medical Review,* pp. 1–30.

[344] De Angelis, G., Posteraro, B., Dr Carolis, E., Menchinelli, G., Franceschi, F., Tumbarello, M., Sanguinetti, M., ''T2Bacteria magnetic resonance assay for the rapid detection of ESKAPEc pathogens directly in whole blood,'' *Journal of Antimicrobial Chemotherapy,* 2018, vol. 73, pp. iv20–iv26, doi:10.1093/jac/dky049.

[345] Nguyen, M. H., Clancy, C., Pasculle, A. W., Pappas, P., Alangaden, G., Pankey, G., Mylonakis, E., ''Clinical performance of the T2Bacteria panel for diagnosis bloodstream infections due to five common bacterial pathogens,'' Manuscript for submission.

[346] De Angelis, G., Posteraro, B., Dr Carolis, E., Menchinelli, G., Franceschi, F., Tumbarello, M., Sanguinetti, M., ''T2Bacteria magnetic resonance assay for the rapid detection of ESKAPEc pathogens directly in whole blood,'' *Journal of Antimicrobial Chemotherapy,* 2018, vol. 73, pp. iv20–iv26, doi:10.1093/jac/dky049.

[347] Clancy, C., & Nguyen, H., ''T2 magnetic resonance for the diagnosis of bloodstream infections: charting a path forward,'' *Journal of Antimicrobial Chemotherapy,* 2018, vol. 73(4), pp. iv2–iv5, doi:10.1093/jac/dky050.

[348] Paul, M., Shani, V., Muchtar, E., Kariv, G., Robenshtok, E., & Leibovici, L., ''Systematic Review and Meta-Analysis of the Efficacy of Appropriate Empiric Antibiotic Therapy for Sepsis,'' *Antimicrobial Agents and Chemotherapy,* 2010, vol. 54(11), pp. 4851–4863.

[349] Castellanos-Ortega, A., Suberviola, B., Garcia-Astudillo, L., Holanda, M., Ortiz, F., Llorca, J., & Delgado-Rodriguez, M., ''Impact of the Surviving Sepsis Campaign Protocols on Hospital Length of Stay and Mortality in Septic Shock Patients: Results of a three-year follow-up quasi-experimental study,'' *Crit Care Med,* 2010, vol. 38(4), pp. 1036–1043, doi:10.1097/CCM.0b0bl3e3181d455b6.

[350] Karlsson, S., Varpula, M., Pettila, V., & Parvlainen, I., ''Incidence, Treatment, and Outcome of Severe Sepsis in ICU-treated Adults in Finland: The Finnsepsis study,'' *Intensive Care Medicine,* 2007, vol. 33, pp. 435–443, doi:10.1007/s00134–006–0504–z.

[351] Suberviola, B., Marquez-Lopez, A., Castellanos-Ortega, A., Fernandez-Mazarrasa, C., Santibanez, M., & Martinez, L., ''Microbiological Diagnosis of Speis: Polymerase chain reaction system versus blood cultures,'' *American Journal of Critical Care,* 2016, vol. 25(1), pp. 68–75.

a reduction in the number of administered antibiotics.[352] The applicant further stated via a supplementary presentation to CMS that the use of the T2Bacteria® Panel allows for earlier species directed therapy than that allowed for by standard-of-care blood cultures. The applicant believed that the use of the T2Bacteria® Panel may allow the provider to move from broad potentially unnecessary empiric to species-targeted therapy. The applicant stated that using hospital antibiograms and being informed of the species by the T2Bacteria® Panel, the physician is able to use species-directed therapy and place up to 90 percent of patients on an effective therapy in a few hours instead of 2 to 3 days.

According to the applicant, the practice of antibiotic de-escalation was recently evaluated across 23 studies and found to be safe and effective.[353] Given the toxicity associated with antibiotics, where some antibiotics cause encephalopathies including seizures [354] and in extreme cases show up to a 4.5 percent mortality rate due to the antibiotic itself,[355] the applicant asserted that judicious use of antibiotics is necessary. The applicant further stated that rapid diagnostics such as that able to be accomplished by the use of the T2Bacteria® Panel assay, due to its negative predictive value (NPV) of 99.7 percent,[356] will enable physicians to focus therapy and reduce the use of unnecessary drugs, where a targeted therapy is possible in 3.8 hours instead of 2 days, reducing toxicity and development of resistance.[357]

The applicant stated that the use of the T2Bacteria® Panel will result in reduced mortality. The applicant indicated that the results of large retrospective analyses show that every hour delaying time to appropriate antibiotic therapy increased odds of death by 4 percent or reduced survival by 7.6 percent.[358] [359] [360] The applicant stated that the results of the T2Bacteria® Panel Pivotal trial show that out of 23 positive patients, 4 (17 percent) could have seen a reduction in time to effective therapy, with mean time of 28.0 hours. An additional 4 (17 percent) could have seen a reduction in time to species-directed therapy, with mean time reduction of 52.6 hours. The applicant stated that by using the T2Bacteria® Panel assay relative to standard-of-care blood cultures, they expect a potential reduction in the odds of death to be 52.8 percent. According to the applicant, this factor of 2 difference is consistent with a two-time higher odds of death in patients given inappropriate empiric antibiotics relative to appropriate empiric antibiotics.[361] The applicant indicated that this result suggests that employing the use of the T2Bacteria® Panel assay should reduce mortality in bacteremia patients who are not immediately on appropriate therapy.

In the form of supplementary information, the applicant stated that the use of the T2Bacteria® Panel covers 5 species, which account for 50 percent to 70 percent of all blood stream infections, depending on local epidemiology. According to the applicant, the remaining 30 percent to 50 percent of patients would continue to need standard-of-care blood cultures for species identification. Based on all of the above, the applicant believed that the T2Bacteria® Test Panel represents a substantial clinical improvement over existing technologies.

We have the following concerns regarding whether the T2Bacteria® Panel meets the substantial clinical improvement criterion. First, we are not certain that the applicant has provided sufficient evidence to demonstrate that the early identification without antibiotic susceptibility provided by the use of the T2 Bacteria® Panel is enough to prevent unnecessary empiric therapy because specific identification and antibiotic susceptibilities may still be required by blood cultures to adequately treat sepsis. For instance, if an on-panel bacteria were identified it remains possible that this species could be resistant to the standard-of-care treatment for such bacteria used in a hospital. In addition, we believe that not only is it possible for an identified species to be resistant to typical empiric therapy, therefore diminishing the utility of its early identification, it also is possible for off-panel organisms to be present and also not be affected by species-targeted empiric treatment. The applicant provided supplemental information in which it stated that consistent with its labeling, the use of the T2Bacteria® Test Panel would not replace blood cultures for specific organisms. Given this information, we are concerned that the use of the T2Bacteria® Panel may not be a substantial clinical improvement over standard-of-care blood cultures, the existing comparator.

Second, the applicant provided research and analyses, which is suggestive that the use of the T2Bacteria® Test Panel may lead to decreased hospital lengths-of-stay, and decreased mortality. Specifically, these analyses and articles show that there is a possibility for a correlated relationship between the T2Bacteria® Panel's time to species ID and these identified outcomes. The applicant addressed this issue in a qualitative manuscript analysis involving identification of potential impacts of the T2Bacteria® Test Panel.[362] We recognize that this qualitative analysis is informative, but we are concerned that the low number of cases (under 10) may limit generalizability of these results. Given this information, we are concerned that in lieu of direct testing, these suggestive

[352] Voigt, C., Silbert, S., Widen, R., Marturano, J., Lowery, T., Ashcraft, D., & Pankey, G., ''The T2Bacteria assay is a sensitive and rapid detector of bacteremia that can be initiated in the emergency department and has potential to favorably influence subsequent therapy,'' *Journal of Emergency Medical Review,* pp. 1–30.

[353] Ohji, G., Doi, A., Yamamoto, S., & Iwata, K., ''Is De-escalation of Antimicrobials Effective? A systematic review and meta-analysis,'' *International Journal of Infectious Diseases,* 2016, vol. 49, pp. 71–79, Retrieved from *http://dx.doi.org/10.1016/j.ijid.2016.06.002.*

[354] Bhattacharyya, S., Darby, R.R., Raibagkar, P., Gonzalez Castro, L.N., & Berkowitz, A., ''Antibiotic-associated Encephalopathy,'' *American Academy of Neurology,* 2016, pp. 963–971.

[355] Koch-Weser, J., Sidel, V., Federman, E., Kanarek, P., Finer, D., & Eaton, A., ''Adverse Effects of Sodium Colistimethate; Manifestations and specific reaction rates during 317 courses of therapy,'' *Annals of Internal Medicine,* 1970, vol. 72, pp. 857–868.

[356] Nguyen, M. H., Clancy, C., Pasculle, A.W., Pappas, P., Alangaden, G., Pankey, G., Mylonakis, E., ''Clinical performance of the T2Bacteria panel for diagnosis bloodstream infections due to five common bacterial pathogens,'' Manuscript for submission.

[357] Weisz, E., Newton, E., Estrada, S., & Saunders, M., ''Early Experience with the T2Bacteria Research Use Only (RUO) Panel at a Community Hospital,'' Lee Memorial Hospital, Fort Meyers.

[358] Paul, M., Shani, V., Muchtar, E., Kariv, G., Robenshtok, E., & Leibovici, L., ''Systematic Review and Meta-Analysis of the Efficacy of Appropriate Empiric Antibiotic Therapy for Sepsis,'' *Antimicrobial Agents and Chemotherapy,* 2010, vol. 54(11), pp. 4851–4863.

[359] Kumar, A., Roberts, D., Wood, K., Light, B., Parrillo, J., Sharma, S., Cheang, M., ''Duration of Hypotension before Initiation of Effective Antimicrobial Therapy is the Critical Determinant of Survival in Human Septic Shock,'' *Crit Care Med,* 2006, vol. 34(6), pp. 1589–1596, doi:10.1097/01.CCM.0000217961.75225.E9.

[360] Seymour, C., Gesten, F., Prescott, H., Friedrich, M., Iwashyna, T., Phillips, G., Levy, M., ''Time to Treatment and Mortality during Mandated Emergency Care for Sepsis,'' *The New England Journal of Medicine,* 2017, vol. 376(23), pp. 2235–2244, doi:10.1056/NEJMoa1703058.

[361] Paul, M., Shani, V., Muchtar, E., Kariv, G., Robenshtok, E., & Leibovici, L., ''Systematic Review and Meta-Analysis of the Efficacy of Appropriate Empiric Antibiotic Therapy for Sepsis,'' *Antimicrobial Agents and Chemotherapy,* 2010, vol. 54(11), pp. 4851–4863.

[362] Voigt, C., Silbert, S., Widen, R., Marturano, J., Lowery, T., Ashcraft, D., & Pankey, G., ''The T2Bacteria assay is a sensitive and rapid detector of bacteremia that can be initiated in the emergency department and has potential to favorably influence subsequent therapy,'' *Journal of Emergency Medical Review,* pp. 1–30.

findings may not show a causative relationship.

Third, we are concerned that in all of the studies provided, the comparator for the T2Bacteria® Panel is a single blood culture draw. It is well established that blood culture sensitivity and specificity increase with repeat blood draws. According to research provided by the applicant, a single set of blood cultures should not be drawn, but rather surveillance blood cultures, involving multiple draws over time, should be practiced.[363] Therefore, we believe that initial blood cultures followed by repeated blood draws would have been a better comparator. Furthermore, we believe an even stronger comparator for the T2Bacteria® Test Panel would be other DNA based tests, such as polymerase chain reaction (PCR), which also utilize DNA to identify bacterial infections.

Ultimately, we are concerned that the use of the T2Bacteria® Test Panel may not alter the clinical course of treatment. We believe that the variable sensitivity and specificity for the T2Bacteria® Panel may be of concern if these results do not compare favorably to other available DNA tests. While some of the false positives in the pivotal trial were explained by reagent contamination (43 of the 63 false positives),[364] the high false positive rate seen in the applicant's literature, (for example, 13 of 32 positives (40.6 percent),[365] 58 of 146 positives (39.7 percent),[366] and a potential 20 of 63 (31.7 percent) from the pivotal trial) may result in unnecessary treatment of patients. Furthermore, use of a contrived arm in the pivotal trial and low overall incidence of these five specific sepsis-causing organisms may make it difficult to determine a substantial clinical improvement in the complex clinical setting. Lastly, it seems that blood cultures may still be necessary to identify species susceptibility because the T2Bacteria® Test Panel does not identify susceptibility and subsequent treatment based upon its results will still require empiric treatment. If these points are true, then the inferred decreased hospital lengths-of-stay, decreased mortality, and better clinical outcomes may not be achieved with the use of the T2Bacteria® Test Panel.

We are inviting public comments on whether the T2Bacteria® Test Panel technology meets the substantial clinical improvement criterion, including with respect to the specific concerns we have raised. We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the T2Bacteria® Test Panel or at the New Technology Town Hall meeting.

q. VENCLEXTA®

AbbVie Pharmaceuticals, Inc. submitted an application for new technology add-on payments for VENCLEXTA® (venetoclax tablets) for FY 2020. According to the applicant, VENCLEXTA® is an oral anti-cancer drug previously FDA-approved for the treatment of patients who have been diagnosed with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA-approved test, who have received at least one prior therapy. VENCLEXTA® received additional FDA approval on November 21, 2018, for the treatment of adult patients who have been diagnosed with CLL or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy, and in combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years old or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

AML is a type of cancer in which the bone marrow makes abnormal myeloblasts (a type of white blood cell), red blood cells, or platelets.[367] The applicant stated that more than half of the patients who are diagnosed with AML annually (19,520) [368] are of Medicare age.[369] The leukemic cells proliferate in the marrow and interfere with production of normal blood cells, causing weakness, infection, bleeding, and other symptoms and complications. In approximately half of these patients, nonrandom chromosomal abnormalities are found by cytogenetic analysis, and these are used for classification, management, and prognostication. AML is generally rapidly lethal unless treated with intensive chemotherapy and/or targeted therapies together with supportive care.[370]

According to the applicant, in younger patients who have been diagnosed with AML, intensive combination chemotherapy is the primary treatment modality.[371] Options for induction chemotherapy include standard or high-dose cytarabine in combination with an anthracycline. The most commonly used induction regimens for diagnoses of AML are the so-called ''7+3'' regimens, which combine a 7-day continuous intravenous infusion of cytarabine with a short infusion or bolus of an anthracycline given on days 1 through 3. The applicant indicated that the most commonly used anthracycline in this regimen is daunorubicin, but other anthracyclines or synthetic anthracycline analogs have been used. Depending on age and patient selection, up to 70 to 80 percent of younger adults achieve complete remission with the use of these regimens.[372] [373]

However, the applicant indicated that older adults over the age of 55 years old [374] are more frequently refractory to such cytotoxic-intensive induction chemotherapy when compared to younger patients because of biological disease-related factors such as increased

[363] Wilson, M., Mitchell, M., Morris, A., Murray, P., Reimer, L., Reller, L. B., Welch, D., ''Prinicples and Procedures for Blood Cultures; Approved Guildeline,'' Clinical and Laboratory Standards Institute, 2007.

[364] T2 Biosystems, Inc., ''T2Bacteria® Panel for use on the T2Dx® Instrument, 510(k) summary,'' Lexington, 2018.

[365] De Angelis, G., Posteraro, B., Dr Carolis, E., Menchinelli, G., Franceschi, F., Tumbarello, M., Sanguinetti, M., ''T2Bacteria magnetic resonance assay for the rapid detection of ESKAPEc pathogens directly in whole blood,'' *Journal of Antimicrobial Chemotherapy,* 2018, vol. 73, pp. iv20–iv26, doi:10.1093/jac/dky049.

[366] Nguyen, M. H., Clancy, C., Pasculle, A. W., Pappas, P., Alangaden, G., Pankey, G., Mylonakis, E., ''Clinical performance of the T2Bacteria panel for diagnosis bloodstream infections due to five common bacterial pathogens,'' Manuscript for submission.

[367] National Cancer Institute, ''Adult Acute Myeloid Leukemia Treatment—Patient Version,'' *https://www.cancer.gov/types/leukemia/patient/adult-aml-treatment-pdq,* Accessed September 11, 2018.

[368] Siegel, R.L., Miller, K.D., Jemal, A., ''Cancer Statistics,'' *CA: A Cancer Journal for Clinicians,* 2018, vol, 68(1), pp. 7–30, doi:10.3322/caac.21442.

[369] National Cancer Institute. ''SEER Stat Fact Sheets: Acute Myeloid Leukemia,'' Bethesda, MD, *http://seer.cancer.gov/statfacts/html/amyl.html,* Accessed September 11, 2018.

[370] Wolters Kluwer Health, ''Overview of acute myeloid leukemia in adults,'' *https://www.uptodate.com/contents/induction-therapy-for-acute-myeloid-leukemia-in-younger-adults,* Accessed October 9, 2018.

[371] Wolters Kluwer Health, ''Induction therapy for acute myeloid leukemia in younger adults,'' *https://www.uptodate.com/contents/induction-therapy-for-acute-myeloid-leukemia-in-younger-adults,* Accessed September 11, 2018.

[372] Ohtake, S., Miyawaki, S., Fujita, H., *et al.,* ''Randomized study of induction therapy comparing standard-dose idarubicin with high-dose daunorubicin in adult patients with previously untreated acute myeloid leukemia: the JALSG AML201 Study,'' *Blood,* 2010, vol. 117(8), pp. 2358–65, doi:10.1182/blood–2010–03–273243.

[373] Fernandez, H.F., Sun, Z., Yao, X., *et al.,* ''Anthracycline Dose Intensification in Acute Myeloid Leukemia,'' *New England Journal of Medicine,* 2009, vol. 361(13), pp. 1249–59, doi:10.1056/nejmoa0904544.

[374] Wolters Kluwer Health, ''Induction therapy for acute myeloid leukemia in younger adults,'' *https://www.uptodate.com/contents/induction-therapy-for-acute-myeloid-leukemia-in-younger-adults,* Accessed September 11, 2018.

frequency of adverse-risk cytogenetic and molecular features, secondary AML, and increased expression of multi-drug resistance phenotypes.[375] Elderly patients also present with more comorbidities and compromised organ function than do younger patients, which means they have decreased tolerance to intensive therapies which can lead to unacceptably high treatment-related mortality.[376] [377] [378] The applicant explained that prognostic algorithms that can predict the probability of achieving a complete response (CR) and the risk for an early death for elderly patients with untreated AML have been developed, and can help a physician determine whether or not the patient is eligible for intensive chemotherapy.[379] For these reasons, only 40 percent of Medicare-aged patients who have been diagnosed with AML receive chemotherapy for the treatment of the disease.[380] The applicant stated that, in patients not considered fit for intensive treatment and who, therefore, were treated with lower intensity regimens of low-dose cytarabine and hydroxyurea, with or without, all-trans retinoic acid for diagnoses of AML and high-risk myelodysplastic syndrome, only 25 percent of the patients on low-dose cytarabine survived for 12 months.[381] According to the applicant, in an international Phase III study comparing the use of azacitidine with conventional care regimens in older patients who had been newly diagnosed with AML, only 18.6 percent of the patients receiving best supportive care survived for 12 months.[382] Accordingly, the applicant believed that more effective, better-tolerated therapies for elderly patients who have been diagnosed with AML are needed.[383]

We note that, the applicant has submitted a request for approval for a unique ICD–10–PCS code to identify procedures involving the administration of VENCLEXTA®, effective for FY 2020.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments. Current treatments include decitabine, azacitidine, low-dose cytarabine, MYLOTARG™, and supportive care such as anti-emetics, transfusions, and antibiotics/antifungals.[384] [385]

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that VENCLEXTA® does not use the same or similar mechanism of action when compared with an existing technology to achieve a therapeutic outcome for patients diagnosed with AML who are ineligible for intensive chemotherapy The applicant stated that VENCLEXTA® is the first and only FDA-approved, selective oral anti-apoptotic B-cell lymphoma 2 (BCL–2) inhibitor, and works by inhibiting the BCL–2 protein, which regulates cell death and is associated with chemotherapy-resistance and poor outcomes in patients who have been diagnosed with AML.[386] The applicant further asserted that VENCLEXTA® is known to synergize with hypomethylating agents (azacitidine/decitabine) and low-dose cytarabine in the treatment of AML.[387] In AML, malignant cells are dependent on BCL–2 and other pro-survival proteins such as MCL–1 for their survival. A hypomethylator like azacitidine increases BCL–2 dependence and sensitivity to VENCLEXTA® through inhibition of MCL–1, therefore sensitizing the cell to VENCLEXTA®-induced apoptosis.[388] [389] The applicant indicated that because the combination of drugs in the recently-approved indication for the treatment of AML is new, and VENCLEXTA® works synergistically when administered as part of this treatment combination, this creates a unique mechanism of action for the treatment of AML.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant asserted that potential cases representing patients who have been diagnosed with CLL who may be eligible for treatment using VENCLEXTA® would be assigned to different MS–DRGs than cases representing patients who have been diagnosed with AML. According to the applicant, potential cases representing patients who have been diagnosed with CLL who may be eligible for treatment using VENCLEXTA® would be assigned to the following MS–DRGs: 808 (Major Hematological And Immunological Diagnoses Except Sickle Cell Crisis And Coagulation Disorders With MCC), 809 (Major Hematological And Immunological Diagnoses Except Sickle Cell Crisis And Coagulation Disorders With CC), 823 (Lymphoma And Non-Acute Leukemia With Other Procedure With MCC), 824 (Lymphoma And Non-Acute Leukemia With Other Procedure With CC), 825 (Lymphoma And Non-Acute Leukemia With Other Procedure Without CC/MCC), 834 (Acute Leukemia Without Major O.R. Procedure With MCC), 835 (Acute Leukemia Without Major O.R. Procedure With CC), 836 (Acute Leukemia Without Major O.R. Procedure Without CC/MCC), and 839

[375] Krug, U., Büchner, T., Berdel, W.E., Müller-Tidow, C., ''The treatment of elderly patients with acute myeloid leukemia,'' *Dtsch Arztebl Int,* 2011, vol. 108, pp. 863–70.

[376] Pettit, K., Odenike, O., ''Defining and treating older adults with acute myeloid leukemia who are ineligible for intensive therapies,'' *Front Oncol,* 2015, vol. 5, pp. 280.

[377] Kantarjian, H., Ravandi, F., O'Brien, S., et al., ''Intensive chemotherapy does not benefit most older patients (age 70 years or older) with acute myeloid leukemia,'' *Blood,* 2010, vol. 116, pp. 4422–9.

[378] Kantarjian, H., O'Brien, S., Cortes, J., et al., ''Results of intensive chemotherapy in 998 patients age 65 years or older with acute myeloid leukemia or high-risk myelodysplastic syndrome: predictive prognostic models for outcome,'' *Cancer,* 2006, vol. 106, pp. 1090–98.

[379] O'Donnell, Margaret R., et al. ''Acute Myeloid Leukemia, Version 3.2017, NCCN Clinical Practice Guidelines in Oncology.'' Journal of the National Comprehensive Cancer Network, vol. 15, no. 7, 2017, pp. 926–957., doi:10.6004/jnccn.2017.0116.

[380] Medeiros, B.C., Satram-Hoang, S., Hurst, D., Hoang, K.Q., Momin, F., Reyes, C., ''Big data analysis of treatment patterns and outcomes among elderly acute myeloid leukemia patients in the United States,'' *Annals of Hematology,* 2015, vol. 94(7), pp. 1127–38, doi:10.1007/s00277–015–2351–x.

[381] Burnett, Alan K., *et al.,* ''A Comparison of Low-Dose Cytarabine and Hydroxyurea with or without All-Trans Retinoic Acid for Acute Myeloid Leukemia and High-Risk Myelodysplastic Syndrome in Patients Not Considered Fit for Intensive Treatment,'' *Cancer,* vol. 109, no. 6, 2007, pp. 1114–1124, doi:10.1002/cncr.22496.

[382] Dombret, H., *et al.,* ''International Phase 3 Study of Azacitidine vs Conventional Care Regimens in Older Patients with Newly Diagnosed AML with >30% Blasts,'' *Blood,* vol. 126, no. 3, 2015, pp. 291–299, doi:10.1182/blood–2015–01–621664.

[383] DiNardo, C.D., Pratz, K.W., Letai, A., *et al.,* ''Safety and preliminary efficacy of venetoclax with decitabine or azacitidine in elderly patients with previously untreated acute myeloid leukemia: a non-randomized, open-label, phase Ib study,'' *The Lancet Oncology,* 2018, vol. 19(2), pp. 216–28, doi:10.1016/s1470–2045(18)30010–x.

[384] Ibid.

[385] Wolters Kluwer Health, ''Induction therapy for acute myeloid leukemia in younger adults,'' *https://www.uptodate.com/contents/induction-therapy-for-acute-myeloid-leukemia-in-younger-adults,* Accessed September 11, 2018.

[386] Pan, R., Hogdal, L.J., Benito, J.M., et al., ''Selective BCL–2 inhibition by ABT–199 causes on-target cell death in acute myeloid leukemia,'' *Cancer Discov,* 2014, vol. 4(3), pp. 362–75.

[387] Bogenberger, J.M., Delman, D., Hansen, N., et al., ''Ex vivo activity of BCL–2 family inhibitors ABT–199 and ABT–737 combined with 5-azacitidine in myeloid malignancies,'' *Leukemia & Lymphoma,* 2014, vol. 56(1), pp. 226–229, doi:10.3109/10428194.2014.910657.

[388] Konopleva, M., et al., ''Efficacy and Biological Correlates of Response in a Phase II Study of Venetoclax Monotherapy in Patients with Acute Myelogenous Leukemia,'' *Cancer Discovery,* vol. 6, no. 10, Dec. 2016, pp. 1106–1117, doi:10.1158/2159–8290.cd–16–0313.

[389] Valentin, Rebecca, et al., ''The Rise of Apoptosis: Targeting Apoptosis in Hematologic Malignancies,'' *Blood,* 2018, vol. 132, no. 12, pp. 1248–1264, doi:10.1182/blood–2018–02–791350.

(Chemotherapy With Acute Leukemia As SDX Without CC/MCC). We believe that potential cases representing patients who have been newly diagnosed with AML, as well as potential cases representing patients who have been diagnosed with CLL, could both be assigned to the following 3 MS–DRGs: 820 (Lymphoma and Leukemia With Major O.R. Procedure With MCC), 821 (Lymphoma and Leukemia With Major O.R. Procedure With CC), and 822 (Lymphoma and Leukemia With Major O.R. Procedure Without CC/MCC). We expect that cases involving treatment with VENCLEXTA® would most likely be assigned to the same MS–DRGs to which cases involving comparable treatments are assigned.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted that VENCLEXTA® does not involve the treatment of the same or similar type of disease or same or similar patient population because there are currently no curative treatment options available for elderly patients who have been newly diagnosed with AML who are ineligible for intensive chemotherapy.

The applicant further asserted that the disease and patient population for which VENCLEXTA® provides treatment is unique. There are no other FDA-approved therapies specific to this patient population—newly diagnosed AML patients who are ineligible for intensive chemotherapy—and currently these patients receive only lower-intensity treatments without curative intent, but rather treatment is focused on alleviating symptoms, prolonging life, and/or improving quality of life.[390] The applicant stated that where patients on intensive chemotherapy have benefited from improvements in overall survival over the past 50 years, ineligible patients have not; and more effective, better-tolerated therapies for elderly patients who have been diagnosed with AML are urgently needed.[391] The applicant further stated that this unmet medical need is one reason why VENCLEXTA® received Breakthrough Therapy designation from the FDA for this patient population.[392]

With respect to whether the technology involves the treatment of a unique patient population, we note that as the applicant indicated, there are lower-intensity chemotherapeutic regimens available as standard-of-care therapies for patients who have been newly diagnosed with AML who are ineligible for intensive chemotherapy. We are inviting public comments on whether VENCLEXTA® is substantially similar to any existing technology and whether it meets the newness criterion, including with respect to the concerns we have raised.

With regard to the cost criterion, the applicant conducted the following analysis. The applicant used the FY 2017 MedPAR Hospital Limited Data Set (LDS) to assess the MS–DRGs to which cases representing potential patient hospitalizations that may be eligible for treatment involving VENCLEXTA® would most likely be assigned. These potential cases representing patients who may be VENCLEXTA® candidates were identified if these cases reported a diagnosis of AML. The cohort was limited by excluding patients who were discharged as not classified with one of the relevant ICD–10–CM codes.

From the resulting data, the applicant determined the most applicable MS–DRGs to use in order to determine the average length-of-stay by identifying the codes with at least 1 percent of total discharge volume, which limited the selection to 16 codes. According to the applicant, in an effort to limit impact from MS–DRGs with probable low relevance and/or not usually representing solely AML inpatient stays, a number of high-volume MS–DRGs were not included in the calculation. These excluded codes included those representing high-dose chemotherapy inpatient stays, sepsis cases, pneumonia inpatient stays, and heart failure and circulation disorders. This left potential cases represented in MS–DRGs 808, 809, 834, 835, 836, and 839 to determine the average length-of-stay, which under this criterion resulted in 7.25 days.

The applicant noted that two limitations of this calculation method are: (1) That the average length-of-stay may have changed since FY 2017 for the MS–DRGs selected; and (2) the approach of relevant case identification may not adequately capture patients who are ineligible for intensive chemotherapy.

The applicant provided additional analyses with the VENCLEXTA® charges under six separate cost threshold scenarios. According to the applicant, the cost criterion was satisfied in each of these scenarios, with charges in excess of the average case-weighted threshold amount. Scenario 1 captures discharges classified with one or more of seven subtypes of patients who have been diagnosed with AML who have not achieved remission or who have been diagnosed with AML in relapse; a subgroup to capture patients who have not been responsive to existing treatments. Scenario 2 captures discharges classified with one or more of seven subtypes of patients who had been diagnosed with AML who never have achieved remission; a population that will have a high concentration of patients who have been newly diagnosed with AML. Lastly, scenario 3 is a combination of all discharges that classified patients who have been diagnosed with AML who have not relapsed.

While the VENCLEXTA® Breakthrough Therapy designation is for use in elderly patients who have been newly diagnosed with AML, the applicant determined it was necessary to produce separate cost threshold calculations based on the three diagnosis code selections pending the final VENCLEXTA® label. Scenarios 1 through 3 have additional exclusions and inclusion codes that: (1) Add comorbidities to patients between 65 years old and 74 years old; (2) remove affects from related non-AML conditions; and (3) ensure that all discharges were administered drugs. Scenarios 4, 5, and 6 use the same base ICD–10–CM inclusion codes as scenarios 1, 2, and 3, respectively, however, they do not use additional inclusion and exclusion codes, which makes the cost threshold results representative of a broader patient population. For each cost threshold scenario, the applicant also applied a deduction of 50 percent of pharmacy charges to account for the replacement of hospital expenditures when VENCLEXTA® is used as first-line therapy.

The applicant produced cost threshold results for 6 scenarios, each with 4 MS–DRGs, for a total of 24 cost threshold calculations. All four MS–DRGs had identical volume percentages in each of the six scenarios. The average dollar amount by which the average case-weighted standardized charges per case exceeded the average case-weighted threshold amount is

[390] Wolters Kluwer Health, ''Acute myeloid leukemia: Treatment and outcomes in older adults,'' *https://www.uptodate.com/contents/acute-myeloid-leukemia-treatment-and-outcomes-in-older-adults,* Accessed September 11, 2018.

[391] DiNardo, C.D., Pratz, K.W., Letai, A., et al., ''Safety and preliminary efficacy of venetoclax with decitabine or azacitidine in elderly patients with previously untreated acute myeloid leukemia: a non-randomized, open-label, phase Ib study,'' *The Lancet Oncology,* 2018, vol. 19(2), pp. 216–28, doi:10.1016/s1470–2045(18)30010–x.

[392] Hoffjman-LaRoche, Ltd., F., ''FDA grants breakthrough therapy designation for VENCLEXTA® in acute myeloid Leukaemia,'' *https://www.roche.com/dam/jcr:0cf1ad70-02c8-44b4-94ac-ccdf1dbca95a/en/inv-update-2017-07-28-e.pdf,* Accessed October 9, 2018.

$17,612.75 for scenario 1, $15,730.27 for scenario 2, $15,566.70 for scenario 3, $33,868.18 for scenario 4, $32,098.60 for scenario 5, and $30,860.67 for scenario 6. The applicant asserted that considering only the most applicable MS–DRGs, MS–DRG 834 and MS–DRG 835, the average case-weighted threshold amounts were exceeded by a range of $16,169.02 at the lowest (scenario 2) and $50,185.99 at the highest (scenario 4) and, therefore, the applicant believes VENCLEXTA® meets the cost criterion.

Based on all of the analyses above, the applicant maintained that VENCLEXTA® meets the cost criterion. We are inviting public comments on whether VENCLEXTA® meets the cost criterion.

With regard to substantial clinical improvement, the applicant asserted that VENCLEXTA®, in combination with either azacitidine or decitabine, and VENCLEXTA®, in combination with low-dose cytarabine, both constitute a substantial clinical improvement over currently available treatments for patients who have been newly diagnosed with AML who are ineligible for intensive chemotherapy. The applicant submitted two main studies to support its assertion that the technology represents a substantial clinical improvement over existing technologies.

The first study submitted was M14–358, a Phase Ib, open-label, multi-center, non-randomized study of the use of VENCLEXTA®, in combination with azacitidine or decitabine, in the treatment of patients who have been newly diagnosed with AML who are not eligible for standard induction therapy. Eligible patients were 60 years old and older, had previously undiagnosed AML, had intermediate- or poor-risk cytogenetics, and were not eligible for standard induction therapy. Patients received VENCLEXTA® via a daily ramp-up to a final 400 mg once-daily dose. During the ramp-up, patients received tumor lysis syndrome (TLS) prophylaxis and were hospitalized for monitoring. Azacitidine at 75 mg/m2 was administered either intravenously or subcutaneously on Days 1 through 7 of each 28-day cycle beginning on Cycle 1 Day 1. Decitabine at 20 mg/m2 was administered intravenously on Days 1 through 5 of each 28-day cycle beginning on Cycle 1 Day 1. Patients continued to receive treatment cycles until disease progression or unacceptable toxicity. Azacitidine dose reduction was implemented in the clinical trial for management of hematologic toxicity. Dose reductions for decitabine were not implemented in the clinical trial.

The primary objective of the escalation stage of this trial was to evaluate the safety and pharmacokinetics of orally-administered VENCLEXTA®, combined with decitabine or azacitidine, at standard doses and schedules in patients who had been newly diagnosed with AML who were 60 years old and older and who are not eligible for standard induction therapy due to comorbidities. Secondary objectives for the dose escalation included assessing the preliminary efficacy of the use of VENCLEXTA® administered orally, in combination with either decitabine or azacitidine, in this patient population. The primary objectives of the expansion stage were to confirm the safety and to assess efficacy including complete remission (CR) and complete remission with incomplete blood count recovery (CRi) and determine overall survival (OS) of the use of VENCLEXTA® combined with decitabine or azacitidine in the treatment of patients who had been newly diagnosed with AML. A secondary objective for the expansion was to evaluate duration of response (DOR). Complete remission was defined as absolute neutrophil count greater than 1,000/microliter, platelets greater than 100,000/microliter, red blood cell transfusion independence, and bone marrow with less than 5 percent blast, absence of circulating blasts and blasts with Auer rods, and absence of extramedullary disease. Complete remission with partial hematological recovery (CRh) was defined as less than 5 percent of blasts in the bone marrow, no evidence of disease, and partial recovery of peripheral blood counts (platelets greater than 50,000/microliter and ANC greater 500/microliter).

The study arm with VENCLEXTA®, in combination with azacitadine, had 67 patients with a mean age of 76 years old (range 61 years old to 90 years old). Eighty-seven percent of this group was white, 64 percent had an ECOG performance status of 0 to 1, and 34 percent had poor cytogenetic risk detected. The study arm with VENCLEXTA®, in combination with decitabine, had 13 patients with a mean age of 75 years old (range 68 years old to 86 years old). Seven-seven percent of this group was white, 92 percent had an ECOG performance status of 0 to 1, and 62 percent had poor cytogenetic risk detected.

For patients who received VENCLEXTA®, in combination with azacitadine, 37.5 percent (95 percent CI 26, 50) achieved CR and 24 percent (95 percent CI 14, 36) achieved CRh. Sixty-one percent of the patients achieved CR or CRh. The median time to first CR or CRh was 1 month (range 0.7 months to 8.9 months), and median observed time in remission for those patients who achieved CR was 5.5 months (range 0.4 months to 30 months) for this group. The median OS was 16.9 months, the 12-month OS estimate was 57 percent, and median duration of response was 21.2 months. For patients who received VENCLEXTA®, in combination with decitabine, 54 percent (95 percent CI, 25 months to 81 months) achieved CR and 8 percent (95 percent CI, 0.2 months to 36 months) achieved CRh. Sixty-two percent of the patients achieved CR or CRh. The median time to first CR or CRh was 1.9 months (range 0.8 months to 4.2 months), and median observed time in remission for those who achieved CR was 4.7 months (range 1 month to 18 months) for this group. The median OS was 16.2 months, the 12-month OS estimate was 61 percent, and median duration of response was 15 months. The study enrolled 35 additional patients (age range 65 years old to 74 years old) who did not have known comorbidities that precluded the use of intensive induction chemotherapy and were treated with VENCLEXTA®, in combination with azacitidine (n=17) or decitabine (n=18). For the additional patients treated with VENCLEXTA®, in combination with azacitidine, the CR rate was 35 percent (95 percent CI 14, 62). The CRh rate was 41 percent (95 percent CI 18, 67). For the additional patients treated with VENCLEXTA®, in combination with decitabine, the CR rate was 56 percent (95 percent CI 31, 79). The CRh rate was 22 percent (95 percent CI 6.4, 48).

In terms of safety, for patients receiving azacitadine, the most common adverse reactions (greater than or equal to 30 percent) of any grade were nausea, diarrhea, constipation, neutropenia, thrombocytopenia, hemorrhage, peripheral edema, vomiting, fatigue, febrile neutropenia, rash, and anemia. Serious adverse reactions were reported in 75 percent of the patients. The most frequent serious adverse reactions (greater than or equal to 5 percent) were febrile neutropenia, pneumonia (excluding fungal), sepsis (excluding fungal), respiratory failure, and multiple organ dysfunction syndrome. The incidence of fatal adverse drug reactions was 1.5 percent within 30 days of starting treatment. No reaction had an incidence of greater than or equal to 2 percent. Discontinuations due to adverse reactions occurred in 21 percent of the patients. The most frequent adverse reactions leading to drug

discontinuation (greater than or equal to 2 percent) were febrile neutropenia and pneumonia (excluding fungal). Dosage interruptions due to adverse reactions occurred in 61 percent of the patients. The most frequent adverse reactions leading to dose interruption (greater than or equal to 5 percent) were neutropenia, febrile neutropenia, and pneumonia (excluding fungal). Dosage reductions due to adverse reactions occurred in 12 percent of the patients. The most frequent adverse reaction leading to dose reduction (greater than or equal to 5 percent) was neutropenia.

For patients receiving decitabine, the most common adverse reactions (greater than or equal to 30 percent) of any grade were febrile neutropenia, constipation, fatigue, thrombocytopenia, abdominal pain, dizziness, hemorrhage, nausea, pneumonia (excluding fungal), sepsis (excluding fungal), cough, diarrhea, neutropenia, back pain, hypotension, myalgia, oropharyngeal pain, peripheral edema, pyrexia, and rash. Serious adverse reactions were reported in 85 percent of the patients. The most frequent serious adverse reactions (greater than or equal to 5 percent) were febrile neutropenia, sepsis (excluding fungal), pneumonia (excluding fungal), diarrhea, fatigue, cellulitis, and localized infection. One (8 percent) fatal adverse drug reaction of bacteremia occurred within 30 days of starting treatment. Discontinuations due to adverse reactions occurred in 38 percent of the patients. The most frequent adverse reaction leading to drug discontinuation (greater than or equal to 5 percent) was pneumonia (excluding fungal). Dosage interruptions due to adverse reactions occurred in 62 percent of the patients. The most frequent adverse reactions leading to dose interruption (greater than or equal to 5 percent) were febrile neutropenia, neutropenia, and pneumonia (excluding fungal). Dosage reductions due to adverse reactions occurred in 15 percent of the patients. The most frequent adverse reaction leading to dose reduction (greater than or equal to 5 percent) was neutropenia.

The second study submitted was M14–387, a non-randomized, open-label Phase I/II study of the use of VENCLEXTA®, in combination with low-dose cytarabine, in patients who had been newly diagnosed with AML who are ineligible for standard anthracycline-based induction therapy. The study enrolled patients who were 60 years old and older who had been diagnosed with AML and who were not eligible for standard induction therapy.

Patients initiated use of VENCLEXTA® via daily ramp-up to a final 600 mg once-daily dose. During the ramp-up, patients received TLS prophylaxis and were hospitalized for monitoring. Cytarabine at a dose of 20 mg/m2 was administered subcutaneously once-daily on Days 1 through 10 of each 28-day cycle beginning on Cycle 1 Day 1.

This study consisted of three distinct portions. The first portion of the study was a Phase I, or dose-escalation portion, that evaluated the safety and pharmacokinetics (PK) profile of VENCLEXTA® administered with low-dose azacitidine with the objectives of defining the maximum-tolerated dose (MTD) and generating data to support a recommended Phase II dose (RPTD). A subsequent initial Phase II portion evaluated whether the RPTD had sufficient efficacy and acceptable toxicity to warrant further development of the combination therapy. Subsequently, a Phase II, Cohort C was enrolled to evaluate the ORR for patients who were allowed additional supportive medications (for example, strong CYP3A inhibitors), if medically indicated, because new PK data emerged from external studies demonstrating that these previously excluded concomitant medications may be tolerable with an appropriate VENCLEXTA® dose adjustment during co-administration.

The primary objectives of the Phase I portion were to assess the safety profile, characterize the (PK), and determine the dose schedule, the MTD, and the RPTD of the use of VENCLEXTA®, in combination with low-dose azacitidine or cytarabine in the treatment of patients who had been newly diagnosed with AML who were 60 years old and older and who were not eligible for standard induction therapy due to co-morbidity or other factors. The primary objectives of the initial Phase II portion of the study were to evaluate the preliminary estimates of efficacy including the overall response rate (ORR) and to characterize the toxicities of the combination at the RPTD. The primary objective of Phase II, Cohort C was to evaluate the ORR for patients allowed additional supportive medications (strong cytochrome P450 [CYP]3A inhibitors), if medically indicated. The secondary objectives of the initial Phase II portion and Phase II, Cohort C were to evaluate leukemia response (rates of complete remission (CR)), complete remission with incomplete blood count recovery (Cri), partial remission (PR), and morphologically leukemia-free status (MLFS)), duration of response (DOR), and OS. Patients continued to receive treatment cycles until disease progression or unacceptable toxicity. Dose reduction for low-dose cytarabine was not implemented in the clinical trial.

The study enrolled 61 patients with a median age of 76 years old (range 63 years old to 90 years old), 92 percent of whom were white, 66 percent of whom had an ECOG performance status of 0 to 1, and 34 percent of whom had poor cytogenetic risk detected. Twenty-one percent (95 percent CI 12, 34) achieved CR and 21 percent (95 percent CI 12, 34) achieved CRh. Overall 43 percent of the patients achieved CR or CRh. The median OS was 10.1 months and median duration of response was 8.1 months. The study enrolled 21 additional patients (age ranged 67 years old to 74 years old) who did not have known comorbidities that precluded the use of intensive induction chemotherapy and were treated with VENCLEXTA®, in combination with low-dose cytarabine. The CR rate was 33 percent (95 percent CI: 15, 57). The CRh rate was 24 percent (95 percent CI: 8.2, 47).

In terms of safety, the most common adverse reactions (greater than or equal to 30 percent) of any grade were nausea, thrombocytopenia, hemorrhage, febrile neutropenia, neutropenia, diarrhea, fatigue, constipation, and dyspnea. Serious adverse reactions were reported in 95 percent of the patients. The most frequent serious adverse reactions (greater than or equal to 5 percent) were febrile neutropenia, sepsis (excluding fungal), hemorrhage, pneumonia (excluding fungal), and device-related infection. The incidence of fatal adverse drug reactions was 4.9 percent within 30 days of starting treatment with no reaction having an incidence of greater than or equal to 2 percent. Discontinuations due to adverse reactions occurred in 33 percent of the patients. The most frequent adverse reactions leading to drug discontinuation (greater than or equal to 2 percent) were hemorrhage and sepsis (excluding fungal). Dosage interruptions due to adverse reactions occurred in 52 percent of the patients. The most frequent adverse reactions leading to dose interruption (greater than or equal to 5 percent) were thrombocytopenia, neutropenia, and febrile neutropenia. Dosage reductions due to adverse reactions occurred in 8 percent of the patients. The most frequent adverse reaction leading to dose reduction (greater than or equal to 2 percent) was thrombocytopenia. On the basis of these studies, the applicant asserted that median OS, 12-month OS, CR + CRi, and DOR for VENCLEXTA® are all substantially higher than the outcomes

achieved by standard-of-care as reported by studies. The applicant asserted that these improvements, especially the more than doubling of the remission rates as compared to other available low-intensity therapies (range reported as 0 to 28 percent), are substantial and clinically meaningful.

In regard to the substantial clinical improvement criterion for VENCLEXTA®, we reviewed the data the applicant provided on outcomes (for example, CR, CRh, CRi, DOR, and OS) using historical controls of other chemotherapeutic regimens used for this target patient population, and we note that the data is lacking information with regard to a direct comparator. The studies did not detail the demographics and outcomes for patients over the age of 75 versus younger patients. We note that the applicant did not provide any information on how many enrolled patients are from the United States. We further note that fatal adverse drug reactions occurred in both submitted studies in patients receiving treatment involving the use of VENCLEXTA®, and dosage interruptions due to adverse events occurred in a significant proportion of the patients receiving the drug. We also are concerned about the lack of conclusive data on the efficacy of VENCLEXTA®.

We are inviting public comments on whether VENCLEXTA® meets the substantial clinical improvement criterion. We did not receive any written public comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for VENCLEXTA® or at the New Technology Town Hall meeting.

6. Request for Information on the New Technology Add-On Payment Substantial Clinical Improvement Criterion

Under the Hospital Inpatient Prospective Payment System (IPPS), CMS has established policies to provide additional payment for new medical services and technologies. Similarly, under the Hospital Outpatient Prospective Payment System (OPPS), CMS has established policies to provide separate payment for innovative medical devices, drugs and biologicals. Sections 1886(d)(5)(K) and (L) of the Act require the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the IPPS, and section 1833(t)(6) of the Act requires the Secretary to provide an additional payment amount, known as a transitional pass–through payment, for the additional costs of innovative medical devices, drugs, and biologicals under the OPPS. The substantial clinical improvement criterion that is used to evaluate a technology that is the subject of an application for new technology add-on payments under the IPPS or an application for the transitional pass-through payment for the additional costs of innovative devices under the OPPS (both categories of technologies are hereafter collectively referred to as ''new technology'') is the subject of the potential revisions discussed in this section to the new technology add-on payment policy's substantial clinical improvement criteria.

Under the IPPS, the regulations at § 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Under this third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries (we refer readers to the September 7, 2001 final rule for a more detailed discussion of this criterion (66 FR 46902)). For more background on add-on payments for new medical services and technologies under the IPPS, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48552).

In the CY 2001 OPPS interim final rule with comment period (65 FR 67798), we implemented the transitional device pass-through payment requirements in section 1833(t)(6) of the Act under our regulation at 42 CFR 419.66. Under § 419.66(b), a medical device must meet the following requirements to be eligible for transitional pass-through payments: (1) If required by FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability; (2) the device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and (3) the device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion. In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Finally, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The devices to be included in the new category must:

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and were not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) The estimated average reasonable costs of the devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoblation, which are exempt from the cost

requirements as specified at §§ 419.66(c)(3) and (e)); and

• Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

For more background on transitional pass-through payments for devices under the OPPS, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.*

CMS posts on its website the application forms (OMB control #: 0938–1347 for IPPS, and OMB control #: 0938–0857 for OPPS) that applicants must use to apply for IPPS new technology add-on payments at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html* and for OPPS transitional pass-through payments for devices at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*). Each application describes the information specifically requested from each applicant, including what information is needed to support claims of substantial clinical improvement. For example, CMS requests that the applicant provide a summary of substantial clinical improvement claim(s), along with the data supporting each claim. For IPPS new technology add-on payments, in order to provide an opportunity for public input prior to publication of each proposed rule, CMS publishes a notice in the **Federal Register** to announce a town hall meeting at the CMS Headquarters Office in Baltimore, MD, which provides an opportunity for public discussion of the substantial clinical improvement criterion for each IPPS application. This meeting can be attended in-person or through a telephone line, and is also live-streamed on the CMS YouTube web page. CMS considers each IPPS applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the applicable deadline, in our evaluation of the new technology add-on payment applications in the IPPS/LTCH PPS proposed rule. For both IPPS and OPPS applicants, CMS summarizes each applicant's claim(s) of substantial clinical improvement as part of its discussion of the entire application in the relevant proposed rule, as well as any concerns regarding those claims. In the relevant final rule for the IPPS, CMS summarizes and responds to public comments received on the proposed rule and presents its decision whether to approve or disapprove the application for additional payment for the technology for the upcoming fiscal year. In the relevant final rule for the OPPS, CMS similarly responds to public comments and discusses its decision to approve or deny the application for separate transitional pass-through payment for the device for the upcoming calendar year.

A stakeholder comment received in response to the most recent New Technology Town Hall meeting held in December 2018 expressed appreciation for CMS' statements in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20278 through 20279) related to the relationship between the data which satisfies FDA designations and the data which satisfies the substantial clinical improvement criterion under the IPPS regulations, and stated that the clarification would help future applicants understand which types of data can serve as the foundation for satisfying the substantial clinical improvement criterion. Commenters also stated that CMS' statements presented in the FY 2019 IPPS/LTCH PPS proposed rule explaining that it accepts a wide range of data, including peer-reviewed articles, study results, letters from major associations, or other evidence that would support the conclusion of substantial clinical improvement were appreciated. However, feedback from applicants for new technology add-on payments and commenters in prior years have indicated that it would be helpful for CMS to provide greater guidance on what constitutes ''substantial clinical improvement.'' We understand that greater clarity regarding what would substantiate the requirements of this criterion would help the public, including innovators, better understand how CMS evaluates new technology applications for add-on payments and provide greater predictability about which applications will meet the criterion for substantial clinical improvement. We are considering potential revisions to the substantial clinical improvement criteria under the IPPS new technology add-on payment policy, and the OPPS transitional pass-through payment policy for devices, and are seeking public comments on the type of additional detail and guidance that the public and applicants for new technology add-on payments would find useful. This request for public comments is intended to be broad in scope and provide a foundation for potential rulemaking in future years.

In addition to this broad request for public comments for potential rulemaking in future years, as discussed in greater detail in section II.H.7. of the preamble of this proposed rule, in order to respond to stakeholder feedback requesting greater understanding of CMS' approach to evaluating substantial clinical improvement, we are soliciting comments from the public on specific changes or clarifications to the IPPS and OPPS substantial clinical improvement criterion that CMS might consider making in the FY 2020 IPPS/LTCH PPS final rule to provide greater clarity and predictability.

In the applications for both the IPPS new technology add-on payment, and for OPPS limited to the transitional pass-through payment for devices, CMS lists the following criteria that it uses to determine whether a new medical service or technology would represent a substantial clinical improvement:

(1) The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

(2) The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.

(3) Use of the technology significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of technologies are the following:

• Reduced mortality rate with use of the device;

• Reduced rate of device-related complications;

• Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process);

• Decreased number of future hospitalizations or physician visits;

• More rapid beneficial resolution of the disease process treatment because of the use of the device;

• Decreased pain, bleeding, or other quantifiable symptom; and

• Reduced recovery time.

CMS considers the totality of the substantial clinical improvement claims and supporting data, as well as public

comments, when evaluating this aspect of each application.

We are requesting feedback on whether new or changed regulatory provisions or new or changed guidance regarding additional aspects of the substantial clinical improvement evaluation process in the following areas would be helpful. Comments we receive in response to the following general questions will inform future rulemaking after the issuance of the final rule for FY 2020:

- What role should substantial clinical improvement play in our payment policies to ensure these policies do not discourage appropriate utilization of new medical services and technologies?
- How should CMS determine what existing technologies are appropriate comparators to new technologies? How should CMS evaluate a technology when its comparators have different measured clinical outcomes?
- Should CMS provide more specificity or greater clarity on the types of evidence or study designs that may be considered by the agency in evaluating substantial clinical improvement?

For example, what data should be used to demonstrate whether the use of the technology substantially improves clinical outcomes for patients relative to existing technologies? To what extent, if any, should the data be focused on the Medicare population? What clinical outcomes data and patient reported measures data should be assessed to demonstrate substantial clinical improvement?

What particular types of study designs, types of inclusion and exclusion criteria, or types of statistical methodologies, either generally or in comparison to existing technologies, could a new technology use to demonstrate that the technology meets the substantial clinical improvement criterion?

Are there certain study designs that are technically or ethically challenging for specific medical technologies and, if so, should that be more explicitly reflected in the regulations?

Should potential limitations related to cross-trial comparisons with any existing therapies be more explicitly reflected in the regulations?

For non-inferiority studies, the goal of such studies is to show that the difference between the new and active control treatment is small—small enough to allow the known effectiveness of the active control, based on its performance in past studies and the assumed effectiveness of the active control in the current study, to support the conclusion that the new technology is also effective. Are there particular instances where non-inferiority studies should be considered sufficient for an evaluation for substantial clinical improvement because a non-inferiority study is the most appropriate study design for a given technology?

- Are there instances where it would be appropriate for CMS to infer substantial clinical improvement (for example, technical or financial challenges to study accrual)?
- Should CMS consider evidence regarding the off-label use of a new technology? If so, what is the appropriate use of that evidence when evaluating a new technology for an FDA approved or cleared indication? Are there other new technology add-on payment or device pass-through payment changes that CMS should consider regarding off-label use?
- We note that, while additional specificity and guidance on substantial clinical improvement may be helpful, this may also have the unintended consequence of limiting future flexibility in the evaluation of future applications, especially as new technologies are continually emerging. How should CMS balance these considerations in the evaluation of new technologies as it considers potential future steps? Towards this end, would it be helpful to the goal of both predictability and flexibility if the agency explained the types of information or evidence that are *not* required for a finding of substantial clinical improvement?
- Currently, our regulations at § 412.87 require that we announce the results of the new technology add-on payment determinations in the **Federal Register** as part of our annual updates and changes to the IPPS. We also are seeking public comments on revising this requirement to allow the new technology add-on payment determinations, including but not limited to determinations of substantial clinical improvement, to be announced annually in the **Federal Register** separate from the annual updates and changes to the IPPS.

7. Potential Revisions to the New Technology Add-On Payment and Transitional Device Pass-Through Payment Substantial Clinical Improvement Criterion for Applications Received Beginning in FY 2020 for IPPS and CY 2020 for OPPS

In addition to future possible rulemaking and further guidance based on the responses to the general questions in the preceding section, we also are considering adopting, in the FY 2020 IPPS/LTCH PPS final rule, the following potential regulatory changes to the substantial clinical improvement criteria for applications received beginning in FY 2020 for IPPS (that is, for FY 2021 and subsequent new technology add-on payment) and beginning in CY 2020 for OPPS, after consideration of the public comments we receive in response to this proposed rule. We also are seeking public comments on whether any or all of these potential regulatory changes might be more appropriate as changes in guidance rather than or in addition to changes to our regulations.

- Adopting a policy in regulation or sub-regulatory guidance that explicitly specifies that the requirement for substantial clinical improvement can be met if the applicant demonstrates that new technology would be broadly adopted among applicable providers and patients. A broad adoption criterion would reflect the choices of patients and providers, and thus the marketplace, in determining whether a technology represents a substantial clinical improvement. This patient-centered approach would acknowledge that patients and providers can together determine the potential for substantial clinical improvement on an individual basis. As part of the policy being considered, we would add a provision at § 412.87(b)(1) and § 419.66(c)(2) stating that ''substantially improves'' means, *inter alia,* broad adoption by applicable providers and patients. We are seeking public comments on whether, if such a provision is finalized, it should specify that a ''majority'' is the appropriate way to further define and specify ''broad adoption'', or if some other measure of ''broad'' (for example, more than the current standard-of-care, more than a particular percentage) is more appropriate. Furthermore, we are seeking public comments on whether to further specify that ''broad adoption'' is in the context of applicable providers and patients for the technology, and does not mean broadly adopted across the entire IPPS or OPPS. We are interested in whether commenters have particular suggestions regarding how, in implementing such a provision, CMS could provide other helpful regulatory clarification or sub-regulatory guidance regarding how ''broad adoption'' could be measured and demonstrated prospectively as a basis for substantial clinical improvement. If adopted, such a policy would establish, by regulation, predictability and clarity regarding the meaning and application of substantial clinical improvement by providing a specific and clear path to one way

substantial clinical improvement can be established.

• Adopting in regulations or through sub-regulatory guidance a definition that the term ''substantially improves'' means, *inter alia,* that the new technology has demonstrated positive clinical outcomes that are different from existing technologies. As part of the policy being considered, we would specify that the term ''improves'' can always be met by comparison to existing technology. Then, we would further specify that such improvement may always be demonstrated by reference and comparison to diagnosis or treatment achieved by existing technology. This would provide a standard for innovators that is predictable and based on comparison to outcomes from existing technologies, and would reflect that an evaluation of ''improvement'' involves a comparison relative to existing technology. If adopted, such a policy, would establish, by regulation or through sub-regulatory guidance, predictability and clarity regarding the meaning and application of substantial clinical improvement by clarifying how existing and new technologies are compared.

• Adopting a policy in regulation or through sub-regulatory guidance that specifies that ''substantially improves'' can be met through real-world data and evidence, including a non-exhaustive list of such data and evidence, but that such evidence is not a requirement. Real-world evidence reflects usage in everyday settings outside of a clinical trial, which is the majority of care delivered in the United States. For example, between 3 percent and 5 percent of patients with cancer are enrolled in a clinical trial.[393]

As part of the policy being considered, the regulation or sub-regulatory guidance would list the kinds of data and evidence and particular findings that CMS would consider in determining whether the technology meets the substantial clinical improvement criterion and that such kinds of data can be sufficient to meet that standard. Then, we would provide a non-exhaustive list of such kinds of data and findings, including: a decreased mortality rate; a reduction in length of stay; a reduced recovery time; a reduced rate of at least one significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a reduction in at least one clinically significant adverse event; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment; an improvement in one or more activities of daily living; or, an improved quality of life. Outcomes relating to quality of life, length of stay, and activities of daily living may reflect meaningful endpoints not often captured by clinical trials or other pivotal trials designed primarily for regulatory purposes. We are seeking public comments on whether we should adopt such a policy and list, and if so, what the list should contain. We also are seeking comments on whether, as a general matter, data exists on patients' experience with new medical devices outside of the clinician's office, on the effects of a treatment on patients' activities of daily living, or on any of the other areas listed above. These comments would at least inform our adoption of a policy in regulations or sub-regulatory guidance. If adopted, such a policy, would establish, by regulation or guidance, predictability and clarity regarding the meaning and application of substantial clinical improvement by providing a specific and clear path to one way substantial clinical improvement can be established.

• To address the impression that a peer-reviewed journal article is required for the agency to find that a new technology meets the requirement for substantial clinical improvement, explicitly adopting a policy in regulations or sub-regulatory guidance that the relevant information for purposes of a finding of substantial clinical improvement may not require a peer-reviewed journal article. We recognize the value of both academic and other traditional and non-traditional emerging sources of information in determining substantial clinical improvement. We are seeking public comments on whether, in addition to making clear that a peer-reviewed journal article is not required, types of relevant information that could be helpful should be specified in such a regulation or guidance to include but not be limited to other particular formats or sources of information, such as consensus statements, white papers, patient surveys, editorials and letters to the editor, systematic reviews, meta-analyses, inferences from other literature or evidence, and case studies, reports or series, in addition to randomized clinical trials, study results, or letters from major associations, whether published or not. If adopted, such a policy, would establish, by regulation or guidance, predictability and clarity that the agency is open, in every case, to all types of information in considering whether a new technology meets the substantial clinical improvement criterion, consistent with our current practice of not requiring any particular type of information.

• Adopting a policy in regulations or sub-regulatory guidance that, if there is a demonstrated substantial clinical improvement based on the use of a new medical service or technology for any subset of beneficiaries, the substantial clinical improvement criterion may be met regardless of the size of that subset patient population. Substantial clinical improvement may be confounded by comorbidities, patient factors, or other concomitant therapies which are not readily controlled in research studies. This potential change recognizes that subset populations may have unique needs. As part of the policy being considered, we would include a statement in regulation or guidance that a technology may meet the ''substantial clinical improvement'' criterion by demonstrating a substantial improvement for any subset of beneficiaries regardless of size. This potential change would reflect that many medical technologies are designed for limited subset populations. Many personalized and precision medicine approaches aspire for ''n=1 therapy.''

We are seeking public comments on whether, in adopting such a policy, we should also specify that the add-on payment would be limited to use in that subset of patient population. If not, why not? For example, if a new technology that treats cancer only demonstrates substantial clinical improvement for a select subset of patients with that diagnosis, should the additional inpatient payments for use of the new technology be limited to only when that new technology is used in the treatment of that select subset of Medicare beneficiaries, and, if so, how could that subset of patient population be defined in advance, and in what circumstances should there be an exception to any such limitation? If such a policy were adopted, how could it be constructed or written to not create new limitations or obstacles to innovation that are not present in our regulations today?

We also are seeking public comments as to whether there are special approaches that CMS should adopt in regulations or through sub-regulatory guidance for new technologies that treat low-prevalence medical conditions in which substantial clinical improvement may be more challenging to evaluate. Specifically, we are seeking comment on how to categorize and specify these conditions, including how to define ''low-prevalence'', whether CMS should adopt any of the potential changes

[393] *https://ascopubs.org/doi/full/10.1200/jop.0922001.*

under consideration in this section which are not adopted more broadly, or any special approaches suggested by commenters. The goal is to establish, by regulation or guidance, predictability and clarity that the substantial clinical improvement criterion can be met, either in all cases or for cases involving low-prevalence medical conditions, regardless of the size of the patient population which would benefit.

- Adopting a policy in regulations or sub-regulatory guidance that specifically addresses that the substantial clinical improvement criterion can be met without regard to the FDA pathway for the technology. As part of the policy being considered, we would clarify in regulation that the notion of ''improvement'' includes situations where there is an extant technology such as a predicate device for 510(k) purposes, and explicitly state that the agency will not require a device to be approved or cleared through a basis other than a 510(k) clearance in order for the device to be considered a substantial clinical improvement. If adopted, the policy described here, would establish, by regulation or guidance, predictability and clarity by clarifying that the substantial clinical improvement criterion can be met without regard to the FDA pathway for the technology, consistent with our current practice.

We are soliciting comments on the potential revisions and regulatory or sub-regulatory changes described above, and also welcome suggestions on other information that would help us clarify and/or modify in the FY 2020 IPPS/LTCH PPS final rule or through sub-regulatory guidance CMS' expectations regarding substantial clinical improvement for payments for new technologies.

8. Proposed Alternative Inpatient New Technology Add-On Payment Pathway for Transformative New Devices

Under section 1886(d)(5)(K)(vi) of the Act, a medical service or technology will be considered a ''new medical service or technology'' if the service or technology meets criteria established by the Secretary after notice and an opportunity for public comment. For a more complete discussion of the establishment of the current criteria for the new technology add-on payment, we refer readers to the September 7, 2001 final rule (66 FR 46913), where we finalized the ''substantial improvement'' criterion to limit new technology add-on payments under the IPPS to those technologies that afford clear improvements over the use of previously available technologies. Specifically, we stated that we would evaluate a request for new technology add-on payments against the following criteria to determine if the new medical service or technology would represent a substantial clinical improvement over existing technologies:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. We also noted examples of outcomes that are frequently evaluated in studies of medical devices.

In the September 7, 2001 final rule (66 FR 46913), we stated that we believed the special payments for new technology should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. We also stated that where such an improvement is not demonstrated, we continued to believe the incentives of the DRG system would provide a useful balance to the introduction of new technologies. In that regard, we also pointed out that various new technologies introduced over the years have been demonstrated to have been less effective than initially thought, or in some cases even potentially harmful. We stated that we believe that it is in the best interest of Medicare beneficiaries to proceed very carefully with respect to the incentives created to quickly adopt new technology.

Since 2001 when we first established the substantial clinical improvement criterion, the FDA programs for helping to expedite the development and review of transformative new technologies that are intended to treat serious conditions and address unmet medical needs (referred to as FDA's expedited programs) have continued to evolve in tandem with advances in medical innovations and technology. We note that at the time of the development of the September 7, 2001 final rule, devices were the predominant new technology entering the market and, therefore, the substantial clinical improvement criterion was developed with innovative new devices as a focus. At the time, the FDA had three expedited programs (Priority Review, Accelerated Approval, and Fast Track) for drugs and biologicals and no expedited programs for devices. Now, as described in FDA guidance (available on the website at: *https://www.fda.gov/downloads/Drugs/Guidances/UCM358301.pdf* and *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf*), there are four expedited FDA programs for drugs (the three expedited FDA programs named above and a fourth, Breakthrough Therapy, which was established in 2012) and one expedited FDA program for devices, the Breakthrough Devices Program. The 21st Century Cures Act (Cures Act) (Pub. L. 144–255) established the Breakthrough Devices Program to expedite the development of, and provide for priority review of, medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions and which meet one of the following four criteria: that represent breakthrough technologies; for which no approved or cleared alternatives exist; that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or the availability of which is in the best interest of patients.

Some stakeholders over the years have requested that new technologies that receive marketing authorization and are part of an FDA expedited program be deemed as representing a substantial clinical improvement for purposes of the inpatient new technology add-on payments, even in the initial rulemaking on this issue. We understand this request would arguably create administrative efficiency because they currently view the two sets of criteria as the same, overlapping, similar, or otherwise duplicative or unnecessary. As discussed in the September 7, 2001 final rule in which we initially adopted the requirement that a new technology must represent a substantial clinical improvement, we proposed to consult a

Federal panel of experts in evaluating new technology under the ''substantial improvement'' criterion. One commenter believed the panel would be unnecessary and that CMS should automatically deem drugs and biologicals approved by FDA that were included in its expedited programs (which the commenter referred to as ''fast track'' processes) as new technology (66 FR 46914). We stated in response that the panel would consider all relevant information (including FDA expedited program approval) in making its determinations. However, we stated that we did not envision an automatic approval process.

Since 2001, we have continued to receive similar comments. More recently, in response to the FY 2019 New Technology Town Hall meeting notice (83 FR 50379) and the meeting, a commenter stated that the Food and Drug Administration Modernization Act of 1997 authorized a category of medical devices that are eligible for FDA Priority Review designation (83 FR 20278). The commenter explained that, to qualify, products must be designated by the FDA as offering the potential for significant improvements in the diagnosis or treatment of the most serious illnesses, including those that are life-threatening or irreversibly debilitating. The commenter indicated that the processes by which products meeting the statutory standard for priority review are considered by the FDA are specified in greater detail in FDA's Expedited Access Pathway Program, and in the 21st Century Cures Act. The commenter believed that the criteria for FDA Priority Review designation of devices are very similar to the substantial clinical improvement criteria and, therefore, devices used in the inpatient setting determined to be eligible for expedited review and approved by the FDA should automatically be considered as meeting the substantial clinical improvement criterion, without further consideration by CMS.

The Administration is committed to addressing barriers to healthcare innovation and ensuring Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes. As detailed in the President's FY 2020 Budget, HHS is pursuing several policies that will instill greater transparency and consistency around how Medicare covers and pays for innovative technology.

Therefore, given the FDA programs for helping to expedite the development and review of transformative new drugs and devices that meet expedited program criteria (that is, new drugs and devices that treat serious or life-threatening diseases or conditions for which there is an unmet medical need), we considered whether it would also be appropriate to similarly facilitate access to these transformative new technologies for Medicare beneficiaries taking into consideration that marketing authorization (that is, Premarket Approval (PMA); 510(k) clearance; the granting of a De Novo classification request; or approval of a New Drug Application (NDA)) for a product that is the subject of one of FDA's expedited programs could lead to situations where the evidence base for demonstrating substantial clinical improvement in accordance with CMS' current standard has not fully developed at the time of FDA marketing authorization (that is, PMA; 510(k) clearance; the granting of a De Novo classification request; or approval of a NDA) (as applicable). We also considered whether FDA marketing authorization of a product that is part of an FDA expedited program is evidence that the product is sufficiently different from existing products for purposes of newness.

After consideration of these issues, and consistent with the Administration's commitment to addressing barriers to healthcare innovation and ensuring Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes, we concluded that it would be appropriate to develop an alternative pathway for transformative medical devices. In situations where a new medical device is part of the Breakthrough Devices Program and has received FDA marketing authorization (that is, the device has received PMA; 510(k) clearance; or the granting of a De Novo classification request), we are proposing an alternative inpatient new technology add-on payment pathway to facilitate access to this technology for Medicare beneficiaries.

Specifically, we are proposing that, for applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of the FDA's Breakthrough Devices Program and received FDA marketing authorization, it would be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS. In light of the criteria applied under the FDA's Breakthrough Device Program, and because the technology may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization, we also are proposing that the medical device would not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. We are proposing to add a new paragraph (c) under § 412.87 to codify this proposed policy; existing paragraph (c) would be redesignated as paragraph (d) and amendments would be made to proposed redesignated paragraph (d) to reflect this proposed alternative pathway and to make clear that a new medical device may only be approved under § 412.87(b) or proposed new § 412.87(c). Under this proposed alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, the FDA) and that is part of the FDA's Breakthrough Devices Program would need to meet the cost criterion under § 412.87(b)(3), as reflected in proposed new § 412.87(c)(3), and would be considered new as reflected in proposed § 412.87(c)(2).

Given the lack of an evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization, we are soliciting public comment on how CMS should weigh the benefits of this proposed alternative pathway to facilitate beneficiary access to transformative new medical devices, including the benefits of mitigating potential delayed access to innovation and adoption, against any potential risks, such as the risk of adverse events or negative outcomes that might come to light later.

We further note that section 1886(d)(5)(K)(ii)(II) of the Act provides for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology. We also are seeking public comments on whether the newness period under the proposed alternative new technology add-on payment pathway for transformative new medical devices should be limited to a period of time sufficient for the evidence base for the new transformative medical device to develop to the point where a substantial clinical improvement determination can be made (for example, 1 to 2 years after approval, depending on whether the transformative new medical device would be eligible for a third year of new

technology add-on payments). We note that, if we were to adopt such a policy in the future, the proposed amended regulation text would be revised accordingly. We further note that the newness period for a transformative new medical device cannot exceed 3 years, regardless of whether it is approved under the current eligibility criteria, the proposed alternative pathway, or potentially first under the proposed alternative pathway, and subsequently under the current eligibility criteria later in its newness period.

As stated above, for the reasons discussed in section I.O. of Appendix A to this proposed rule, we are not proposing an alternative inpatient new technology add-on payment pathway for drugs at this time.

9. Proposed Change to the Calculation of the Inpatient New Technology Add-On Payment

As noted earlier, section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for a new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. As discussed in the September 7, 2001 final rule, in deciding which treatment is most appropriate for any particular patient, it is expected that physicians would balance the clinical needs of patients with the efficacy and costliness of particular treatments. In the May 4, 2001 proposed rule (66 FR 22695), we stated that we believed it is appropriate to limit the additional payment to 50 percent of the additional cost of the new technology to appropriately balance the incentives. We stated that this proposed limit would provide hospitals an incentive for continued cost-effective behavior in relation to the overall costs of the case. In addition, we stated that we believed hospitals would face an incentive to balance the desirability of using the new technology versus the old; otherwise, there would be a large and perhaps inappropriate incentive to use the new technology.

As such, the current calculation of the new technology add-on payment is based on the cost to hospitals for the new medical service or technology. Specifically, under § 412.88, if the costs of the discharge (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology or medical service.

Since the 50-percent limit to the new technology add-on payment was first established, we have received feedback from stakeholders that our current policy does not adequately reflect the costs of new technology and does not sufficiently support healthcare innovations. For example, stakeholders have stated that a maximum add-on payment of 50 percent does not allow for accurate payment of a new technology with an unprecedented high cost, such as the CAR T-cell technologies KYMRIAH® and YESCARTA® (83 FR 41173).

After consideration of the concerns raised by commenters and other stakeholders, and consistent with the Administration's commitment to addressing barriers to healthcare innovation and ensuring Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes, we agree that there may be merit to the recommendations to increase the maximum add-on amount, and that capping the add-on payment amount at 50 percent could in some cases no longer provide a sufficient incentive for the use of a new technology. Costs of new medical technologies have increased over the years to the point where 50 percent of the estimated cost may not be adequate, and we have received feedback that hospitals may potentially choose not to provide certain technologies for that reason alone.

At the same time, we continue to believe that it is important to preserve the incentives inherent under an average-based prospective payment system through the use of a percentage of the estimated costs of a new technology or service. We stated in the September 7, 2001 final rule (66 FR 46919) that we do not believe it is appropriate to pay an add-on amount equal to 100 percent of the costs of new technology because there is no similar methodology to reduce payments for cost-saving technology. For example, as new technologies permit the development of less-invasive surgical procedures, the total costs per case may begin to decline as patients recover and leave the hospital sooner. Finally, we stated our concern that, because these payments are linked to charges submitted by hospitals, there is the potential that hospitals may adapt their charge structure to maximize payments for DRGs that include eligible new technologies. The higher the marginal cost factor, the greater the incentive hospitals face in this regard.

It is challenging to determine empirically a precise payment percentage between the current 50 percent and 100 percent payment that would be the most appropriate. We believe that 65 percent is an incremental increase that would reasonably balance the need to maintain the incentives inherent to the prospective payment system while also encouraging the development and use of new technologies.

Therefore, we are proposing that, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. Unless the discharge qualifies for an outlier payment, the additional Medicare payment would be limited to the full MS–DRG payment plus 65 percent of the estimated costs of the new technology or medical service. We also are proposing to revise paragraphs (a)(2) and (b) under § 412.88 to reflect these proposed changes to the calculation of the new technology add-on payment amount beginning in FY 2020.

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A

discussion of the proposed FY 2020 hospital wage index based on the statistical areas appears under section III.A.2. of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. (CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, and IV. The OMB control number for approved collection of this information is 0938–0050.) This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2020 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.I. of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2020 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply to the FY 2020 wage index appears under sections III.E.3. and F. of the preamble of this proposed rule.

2. Core-Based Statistical Areas (CBSAs) for the Proposed FY 2020 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion of our implementation of the OMB labor market area delineations beginning with the FY 2015 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2016, beginning with the FY 2017 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 15–01, we refer readers to the FY 2017 IPPS/LTCH PPS final rule. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we continued to use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin No. 15–01 specified in the FY 2017 IPPS/LTCH PPS final rule.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provide detailed information on the update to statistical areas since July 15, 2015, and are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41363), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2018, beginning with the FY 2019 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 17–01, we refer readers to the FY 2019 IPPS/LTCH PPS final rule.

For FY 2020, we are continuing to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01.

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. There are two different lists of codes associated with counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the hospital wage index. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we have learned that SSA county codes are no longer being maintained and updated. However, the FIPS codes continue to be maintained by the U.S. Census Bureau. We believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/geo/reference/county-changes.html.* We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we adopted a policy to discontinue the use of the SSA county codes and began using only the FIPS county codes for purposes of crosswalking counties to

CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates which were effective October 1, 2017, beginning with the FY 2018 wage indexes. These updates have been used to calculate the wage indexes in a manner generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule.

For FY 2020, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs. For FY 2020, Tables 2 and 3 associated with this proposed rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect these county changes.

B. Worksheet S–3 Wage Data for the Proposed FY 2020 Wage Index

The proposed FY 2020 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2016 (the FY 2019 wage indexes were based on data from cost reporting periods beginning during FY 2015).

1. Included Categories of Costs

The proposed FY 2020 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty);
- Home office costs and hours;
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)); and
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2019, the proposed wage index for FY 2020 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2020 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract labor costs, are excluded from the calculation of the wage index.

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

C. Verification of Worksheet S–3 Wage Data

The wage data for the proposed FY 2020 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report (Form CMS–2552–10, OMB Control Number 0938–0050) for cost reporting periods beginning on or after October 1, 2015, and before October 1, 2016. For wage index purposes, we refer to cost reports during this period as the ''FY 2016 cost report,'' the ''FY 2016 wage data,'' or the ''FY 2016 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the proposed FY 2020 wage index includes FY 2016 data submitted to us as of February 7, 2019. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2020 wage index, we identified and excluded 81 providers with aberrant data that should not be included in the wage index, although if data elements for some of these providers are corrected, we intend to include data from those providers in the final FY 2020 wage index. We also adjusted certain aberrant data and included these data in the proposed wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than March 22, 2019. In addition, as a result of the April and May appeals processes, and posting of the April 30, 2019 PUF, we may make additional revisions to the FY 2020 wage data, as described further below. The revised data would be reflected in the FY 2020 IPPS/LTCH PPS final rule.

Among the hospitals we identified and excluded with aberrant data that should not be included in the proposed FY 2020 wage index are eight hospitals that are part of a health care delivery system that is unique in several ways. The vast majority of the system's hospitals (38) are located in a single State, with one union representing most of their hospital employees in the ''northern'' region of the State, while another union represents most of their hospital employees in the ''southern'' region of the State. The salaries negotiated do not reflect competitive local labor market salaries; rather, the salaries reflect negotiated salary rates for the ''northern'' and ''southern'' regions of the State respectively. For example, all medical assistants in the ''northern'' region start at $24.31 per hour, and medical assistants in the ''southern'' region start at $20.36 per hour. Thus, all salaries for similar positions and levels of experience in the northern region, for example, are the same regardless of prevailing labor market conditions in the area in which the hospital is located. In addition, this chain is part of a managed care organization and an integrated delivery system wherein the hospitals rely on the system's health care plans for funding. For the FY 2020 proposed wage index calculation, we have identified and excluded eight of the hospitals that are part of this health

care system. The average hourly wages of these eight hospitals differ most from their respective CBSA average hourly wages, and there is a large gap between the average hourly wage of each of the eight hospitals and the next closest average hourly wage in their respective CBSAs. We do not believe that the average hourly wages of these eight hospitals accurately reflect the economic conditions in their respective labor market areas during the FY 2016 cost reporting period. Therefore, we believe the inclusion of the wage data for these eight hospitals in the proposed wage index would not ensure that the FY 2020 wage index represents the relative hospital wage level in the geographic area of the hospital as compared to the national average of wages. Rather, the inclusion of these data would distort the comparison of the average hourly wage of each of these hospitals' labor market areas to the national average hourly wage. We believe that under section 1886(d)(3)(E) of the Act, which requires the Secretary to establish an adjustment factor (the wage index) reflecting the relative hospital wage level in the geographic area of a hospital compared to the national average hospital wage level, we have the discretion to remove hospital data from the wage index that is not reflective of the relative hospital wage level in the hospitals' geographic area. In previous rulemaking (80 FR 49491), we explained that we remove hospitals from the wage index because their average hourly wages are either extraordinarily high or extraordinarily low compared to their labor market areas, even though their data were properly documented. For this reason, we have removed the data of other hospitals in the past; for example, data from government-owned hospitals and hospitals providing unique or niche services which affect their average hourly wages. We note that we are considering removing all of the hospitals in this health care system from the FY 2021 and subsequent wage index calculations, not because they are failing edits due to inaccuracy, but because of the uniqueness of this chain of hospitals, in particular, the fact that the salaries of their employees are not based on local labor market rates.

In constructing the proposed FY 2020 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2016, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398); that is, any hospital that is designated as a CAH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index. For this proposed rule, we removed 4 hospitals that converted to CAH status on or after January 26, 2018, the cut-off date for CAH exclusion from the FY 2019 wage index, and through and including January 24, 2019, the cut-off date for CAH exclusion from the FY 2020 wage index. After excluding CAHs and hospitals with aberrant data, we calculated the proposed wage index using the Worksheet S–3, Parts II and III wage data of 3,221 hospitals.

For the proposed FY 2020 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located in the same manner that we allotted such hospitals' data in the FY 2019 wage index (83 FR 41364 through 41365); that is, using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the proposed FY 2020 wage index associated with this proposed rule (available via the internet on the CMS website), includes separate wage data for the campuses of 17 multicampus hospitals. The following chart lists the multicampus hospitals by CSA certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

CCN of multicampus hospital	Full-time equivalent (FTE) percentages
050121	0.83
05B121	0.17
070033	0.92
07B033	0.08
100029	0.54
10B029	0.46
100167	0.39
10B167	0.61
140010	0.83
14B010	0.17
220074	0.86
22B074	0.14
330195	0.90
33B195	0.10
330234	0.73
33B234	0.27
340115	0.96
34B115	0.04
360020	0.99
36B020	0.01
370041	0.89
37B041	0.11
390006	0.94
39B006	0.06
390115	0.86
39B115	0.14
390142	0.83
39B142	0.17
460051	0.82
46B051	0.18
510022	0.95
51B022	0.05
670062	0.55
67B062	0.45

We note that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other, variable, digits in the CCN.

D. Method for Computing the Proposed FY 2020 Unadjusted Wage Index

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 41365), we indicated we were committed to transforming the health care delivery system, including the Medicare program, by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. One key to that transformation is ensuring that the Medicare payment rates are as accurate and appropriate as possible, consistent with the law. We invited the public to submit comments, suggestions, and recommendations for regulatory and policy changes to address wage index disparities. Our proposals for FY 2020 to address wage index disparities, particularly for rural hospitals, to the extent permitted under current law, are discussed in section III.N. of the preamble to this proposed rule. We continue to believe that broader statutory wage index reform is needed.

1. Proposed Methodology for FY 2020

The method used to compute the proposed FY 2020 wage index without an occupational mix adjustment follows the same methodology that we used to compute the proposed wage indexes without an occupational mix adjustment since FY 2012 (76 FR 51591 through 51593), except as discussed below. Typically, we do not restate all of the steps of the methodology to compute the wage indexes in each proposed and final rulemaking; instead, we refer readers to the FY 2012 IPPS/LTCH PPS final rule. However, below in this FY 2020 IPPS/LTCH PPS proposed rule, we are (1) restating the steps of the methodology in order to update outdated references to certain cost report lines which were then reflected on Medicare CMS Form 2552–96 but are now reflected on Medicare CMS Form 2552–10; (2) proposing to change the calculation of the Overhead Rate in Step 4; (3) proposing to modify our methodology with regard to how dollar amounts, hours, and other numerical values in the wage index calculation are rounded; and (4) proposing a methodology for calculating the wage index for urban areas without wage data. We are otherwise not proposing to make any other policy changes in this section to the methodology set forth in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 51591 through 51593) for computing the proposed wage index without an occupational mix adjustment. Unless otherwise specified, all cost report line references below refer to CMS Form 2552–10.

Step 1.—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the proposed wage index (in this case, for FY 2020, these would be data from cost reports for cost reporting periods beginning on or after October 1, 2015, and before October 1, 2016). In addition, we include data from some hospitals that had cost reporting periods beginning before October 2015 and reported a cost reporting period covering all of FY 2016. These data are included because no other data from these hospitals would be available for the cost reporting period described above, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2016 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2016 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2015, and before October 1, 2016), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2.—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33, and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35.) In calculating a hospital's Net Salaries (we note that we previously used the term ''average'' salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use the term ''net'' salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10))

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, and 15, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4.

The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15) + (Line 17 + Line 22 + 25.50 + 25.51 + 25.52)

Step 3.—Hours.—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2.

The formula for Total Hours (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15).

Step 4.—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ''excluded rate'', which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula: (Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43).

We then compute the amounts of overhead salaries and hours to be allocated to excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to excluded areas using three steps:

(1) We determine the ''overhead rate'' (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals

typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines.

The formula for the Overhead Rate (from Worksheet S–3, Part II) has been the following: (Lines 26 through 43 − Lines 28, 33 and 35)/((((Line 1 + Lines 28, 33, 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 26 through 43)) − (Lines 9, 10, 28, 33, and 35)) + (Lines 26 through 43 − Lines 28, 33, and 35)).

We note that, for the calculation for FY 2020 and subsequent fiscal years, we are reexamining this step above regarding removal of the sum of overhead contract labor hours on Lines 28, 33, and 35. In the denominator of this calculation of the overhead rate, we have been subtracting out the sum of the overhead contract labor hours from Revised Total Hours. However, this requires modification because Revised Total Hours do not include these overhead contract labor hours. We are proposing to modify this step of the calculation of the overhead rate as follows:

The formula for the Overhead Rate (from Worksheet S–3, Part II) would be the following: (Lines 26 through 43 − Lines 28, 33 and 35)/((((Line 1 + Lines 28, 33, 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) − (Lines 9 and 10)) + (Lines 26 through 43 − Lines 28, 33, and 35)).

(2) We compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.

(3) We multiply the computed overhead wage-related costs by the above excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5.—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2015 through April 15, 2017, for private industry hospital workers from the BLS' Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing to make any changes to the usage for FY 2020. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

Step 6.—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), section 1886(d)(8)(E), or section 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7.—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8.—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

Step 9.—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10.—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage index), we are proposing that, for FY 2020 and subsequent years' wage index calculations, such CBSA's wage index would be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8. We believe that, in the absence of wage data for an urban labor market area, it is reasonable to propose to use a statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology.

For calculation of the proposed FY 2020 wage index, we note there are 2 urban CBSAs for which we do not have IPPS hospital wage data. In Table 3 associated with this proposed rule (which is available via the internet on the CMS website) which contains the area wage indexes, we are including a footnote to indicate to which CBSAs this proposed policy would apply. We are proposing that these CBSAs' wage indexes would be equal to total urban salaries plus wage-related costs (from Step 5) in the respective State, divided by the total urban hours (from Step 4) in the respective State, divided by the national average hourly wage (from Step 8). Under this step, we also are proposing to apply our proposed policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded.

We refer readers to section II. of the Appendix of this proposed rule for the policy regarding rural areas that do not have IPPS hospitals.

Step 11.—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 2 which is listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website.

As we noted previously in this section, we are proposing to modify our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, in order to help ensure consistency in the calculation. For example, we have received questions from stakeholders who use data printed in our proposed and final rules and online in our public use files (PUFs) to calculate the wage indexes, and it has come to our attention that, due in part to occasional inconsistencies in rounding of data,

CMS' calculations and stakeholders' calculations may not match. Therefore, to help ensure consistency in the calculation, we are proposing to modify how the wage data numbers are rounded, as follows. For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we are proposing to use such data ''as is,'' and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we are proposing to round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we are proposing to round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we are proposing to round such numbers to 5 decimals. However, we are proposing to continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2015, through April 15, 2017, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage of the ECI for FY 2020. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/2015	11/15/2015	1.03058
11/14/2015	12/15/2015	1.02885
12/14/2015	01/15/2016	1.02708
01/14/2016	02/15/2016	1.02532
02/14/2016	03/15/2016	1.02357
03/14/2016	04/15/2016	1.02177
04/14/2016	05/15/2016	1.01988
05/14/2016	06/15/2016	1.01790
06/14/2016	07/15/2016	1.01585
07/14/2016	08/15/2016	1.01375
08/14/2016	09/15/2016	1.01162
09/14/2016	10/15/2016	1.00952
10/14/2016	11/15/2016	1.00751
11/14/2016	12/15/2016	1.00560
12/14/2016	01/15/2017	1.00374
01/14/2017	02/15/2017	1.00187
02/14/2017	03/15/2017	1.00000
03/14/2017	04/15/2017	0.99818

For example, the midpoint of a cost reporting period beginning January 1, 2016, and ending December 31, 2016, is June 30, 2016. An adjustment factor of 1.01585 was applied to the wages of a hospital with such a cost reporting period.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico-specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico-specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2020, there is no Puerto Rico-specific overall average hourly wage or wage index.

Based on the above methodology, the proposed unadjusted national average hourly wage is the following:

Proposed FY 2020 Unadjusted National Average Hourly Wage	$44.03

2. Policies Regarding Rural Reclassification and Special Statuses for Multicampus Hospitals

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41369 through 41374), we codified policies regarding rural reclassification and special statuses for multicampus hospitals in the regulations at § 412.92 for sole community hospitals (SCHs), § 412.96 for rural referral centers (RRCs), § 412.103 for rural reclassification, and § 412.108 for Medicare-dependent, small rural hospitals (MDHs).

We stated that these policies apply to hospitals that have a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the IPPS and that meet the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, also referred to as multicampus hospitals or hospitals with remote locations. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41369), a main campus of a hospital cannot obtain an SCH, RRC, or MDH status or rural reclassification independently or separately from its remote location(s), and vice versa. Rather, if the criteria are met in the regulations at § 412.92 for SCHs, § 412.96 for RRCs, § 412.103 for rural reclassification, or § 412.108 for MDHs, the hospital (that is, the main campus and its remote location(s)) will be granted the special treatment or rural reclassification afforded by the aforementioned regulations.

We stated that, to qualify for rural reclassification or SCH, RRC, or MDH status, a hospital with remote locations must demonstrate that both the main campus and its remote location(s) satisfy the relevant qualifying criteria. If the regulations at § 412.92, § 412.96, § 412.103, and § 412.108 require data, such as bed count, number of discharges, or case-mix index, for example, to demonstrate that the hospital meets the qualifying criteria, the combined data from the main campus and its remote location(s) are to be used.

For other qualifying criteria set forth in the regulations at §§ 412.92, 412.96, 412.103, and 412.108 that do not involve data that can be combined, specifically qualifying criteria related to location, mileage, travel time, and distance requirements, a hospital would need to demonstrate that the main campus and its remote location(s) each independently satisfy those requirements in order for the entire hospital, including its remote location(s), to be reclassified or obtain a special status.

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41369 through 41374) for a detailed discussion of our policies for multicampus hospitals.

E. Proposed Occupational Mix Adjustment to the FY 2020 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2016 Medicare Wage Index Occupational Mix Survey for the FY 2019, FY 2020, and FY 2021 Wage Indexes

Section 304(c) of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We collected data in 2013 to compute the occupational mix adjustment for the FY 2016, FY 2017, and FY 2018 wage indexes. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19903) and final rule (82 FR 38137), a new measurement of occupational mix (the 2016 survey) was required for FY 2019, FY 2020, and FY 2021.

The FY 2020 occupational mix adjustment is based on the calendar year (CY) 2016 survey. Hospitals were required to submit their completed 2016 surveys (Form CMS–10079, OMB number 0938–0907) to their MACs by July 3, 2017. The preliminary, unaudited CY 2016 survey data were posted on the CMS website on July 12, 2017. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2020 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

2. Calculation of the Occupational Mix Adjustment for FY 2020

For FY 2020, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2020 wage index. As we explained in section III.D. of the preamble of this proposed rule, we are proposing to modify our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, in order to ensure consistency in the calculation. For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we are proposing to use these data ''as is'', and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we are proposing to round such dollar amounts to 2 decimals. We are proposing to round any hour amounts within the wage index calculations to the nearest whole number. We are proposing to round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we are proposing to continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this proposed rule (which is available via the internet on the CMS website), which contains the proposed FY 2020 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C. of the preamble of this proposed rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2020 wage index. For the proposed FY 2020 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,221 hospitals, and we are using the occupational mix surveys of 3,119 hospitals for which we also have Worksheet S–3 wage data, which represented a ''response'' rate of 97 percent (3,119/3,221). For the proposed FY 2020 wage index, we are applying proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2020 occupational mix adjusted national average hourly wage is the following:

Proposed FY 2020 Occupational Mix Adjusted National Average Hourly Wage ..	$43.99

F. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2020 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this proposed rule, for FY 2020, we are proposing to apply the occupational mix adjustment to 100 percent of the FY 2020 wage index. We calculated the proposed occupational mix adjustment using data from the 2016 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

The proposed FY 2020 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows. (We note that the average hourly wage figures are rounded to two decimal places as we are proposing in section III.D. of the preamble of this proposed rule.)

Occupational mix nursing subcategory	Average hourly wage
National RN	$41.54
National LPN and Surgical Technician	24.67
National Nurse Aide, Orderly, and Attendant	16.95
National Medical Assistant	18.14
National Nurse Category	34.91

The proposed national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2016 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 42 percent, and the national percentage of hospital employees in the all other occupations category is 58 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 27 percent in one CBSA to a high of 82 percent in another CBSA.

We compared the FY 2020 proposed occupational mix adjusted wage indexes for each CBSA to the proposed unadjusted wage indexes for each CBSA. Applying the proposed occupational mix adjustment to the wage data resulted in the following:

COMPARISON OF THE FY 2020 PROPOSED OCCUPATIONAL MIX ADJUSTED WAGE INDEXES TO THE PROPOSED UNADJUSTED WAGE INDEXES BY CBSA

Number of Urban Areas Wage Index Increasing	233 (56.8 percent).
Number of Rural Areas Wage Index Increasing	23 (48.9 percent).
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	113 (27.6 percent).
Number of Urban Areas Wage Index Increasing by 5 percent or More	7 (1.7 percent).
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	10 (21.3 percent).
Number of Rural Areas Wage Index Increasing by 5 Percent or More	0 (0 percent).
Number of Urban Areas Wage Index Decreasing	175 (42.7 percent).
Number of Rural Areas Wage Index Decreasing	24 (51.1 percent).
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	80 (19.5 percent).
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	1 (0.2 percent).
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	7 (14.9 percent).
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	0 (0 percent).
Largest Proposed Positive Impact for an Urban Area	6.39 percent.
Largest Proposed Positive Impact for a Rural Area	3.82 percent.
Largest Proposed Negative Impact for an Urban Area	5.90 percent.
Largest Proposed Negative Impact for a Rural Area	1.66 percent.
Urban Areas Unchanged by Application of the Proposed Occupational Mix Adjustment	2.
Rural Areas Unchanged by Application of the Proposed Occupational Mix Adjustment	0.

These results indicate that a larger percentage of urban areas (56.8 percent) would benefit from the occupational mix adjustment than would rural areas (48.9 percent).

G. Proposed Application of the Rural Floor, Summary of Expired Imputed Floor Policy, and Proposed Application of the State Frontier Floor

1. Proposed Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the ''rural floor''. Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the proposed FY 2020 wage index associated with this proposed rule (which is available via the internet on the CMS website) and our proposal, as discussed in section III.N. of the preamble of this proposed rule, to calculate the rural floor without the wage data of hospitals that have reclassified as rural under § 412.103, we estimated that 166 hospitals would receive an increase in their FY 2020 proposed wage index due to the application of the rural floor.

2. Summary of Expired Imputed Floor Policy

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41376 through 41380), the imputed floor under both the original methodology and the alternative methodology expired on September 30, 2018. As such, the wage index and impact tables associated with this FY 2020 IPPS/LTCH PPS proposed rule (which are available on the internet via the CMS website) do not reflect the imputed floor policy, and we are not applying a national budget neutrality adjustment for the imputed floor for FY 2020. For a complete discussion, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41376 through 41380). As discussed in section III.N. of the preamble of this proposed rule, we are seeking public comments on proposals to help address wage index disparities under the IPPS. We also are seeking public comments on how the expiration of the imputed floor has impacted hospitals in FY 2019.

3. Proposed State Frontier Floor for FY 2020

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) In this FY 2020 IPPS/LTCH PPS proposed rule, we are not proposing any changes to the frontier floor policy for FY 2020. In this proposed rule, 45 hospitals would receive the frontier floor value of 1.0000 for their FY 2020 wage index. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming.

The areas affected by the proposed rural and frontier floor policies for the proposed FY 2020 wage index are identified in Table 2 associated with this proposed rule, which is available via the internet on the CMS website.

H. Proposed FY 2020 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Prior to FY 2016, the wage index tables had consisted of 12 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 9A, and 9C) that were made available via the internet on the CMS website. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41380), beginning with FY 2019, we added Table 4 which is titled and includes a ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' for the relevant fiscal year. We refer readers to section VI. of the Addendum to this proposed rule for a discussion of the proposed wage index tables for FY 2020.

I. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. For reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, we provided that a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; such a hospital receives a reclassified urban wage index during the years of its active MGCRB reclassification and is still considered rural under section 1886(d) of the Act and for other purposes.

We discussed that when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. We exclude hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we consider the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930) for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations.

2. MGCRB Reclassification and Redesignation Issues for FY 2020

a. FY 2020 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280.

At the time this proposed rule was constructed, the MGCRB had completed its review of FY 2020 reclassification requests. Based on such reviews, there are 357 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2020. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2020, hospitals reclassified beginning in FY 2018 or FY 2019 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 332 hospitals approved for wage index reclassifications in FY 2018 that will continue for FY 2020, and 274 hospitals approved for wage index reclassifications in FY 2019 that will continue for FY 2020. Of all the hospitals approved for reclassification for FY 2018, FY 2019, and FY 2020, based upon the review at the time of this proposed rule, 963 hospitals are in a MGCRB reclassification status for FY 2020 (with 32 of these hospitals reclassified back to their geographic location).

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications were included in the FY 2008 IPPS final rule (72 FR 47333) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150).

Changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2020 will be incorporated into the wage index values published in the FY 2020 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value that redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

Applications for FY 2021 reclassifications (OMB control number 0938–0573) are due to the MGCRB by September 3, 2019 (the first working day of September 2019). We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained beginning in mid-July 2019, via the internet on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html,* or by calling the MGCRB at (410) 786–1174.

b. Proposed Elimination of Copy Requirement to CMS

Under regulations in effect prior to FY 2018 (42 CFR 412.256(a)(1)), applications for reclassification were required to be mailed or delivered to the MGCRB, with a copy to CMS, and were not allowed to be submitted through the facsimile (FAX) process or by other electronic means. Because we believed this previous policy was outdated and overly restrictive and to promote ease of application for FY 2018 and subsequent years, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56928), we revised this policy to require applications and supporting documentation to be submitted via the method prescribed in instructions by the MGCRB, with an electronic copy to CMS.

Beginning with applications from hospitals to reclassify for FY 2020, the MGCRB requires applications, supporting documents, and subsequent correspondence to be filed electronically through the MGCRB module of the Office of Hearings Case and Document Management System (''OH CDMS''). Also, the MGCRB issues all of its notices and decisions via email and these documents are accessible electronically through OH CDMS. Registration instructions and the system user manual are available at: *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/Electronic-Filing.html.*

Filing a reclassification application using OH CDMS entails completing required fields electronically and uploading supporting documentation. We believe that the requirement for hospitals to submit a copy of the application to CMS would now require hospitals to compile their application information in a different format than what is required by the MGCRB, which would result in additional burden for hospitals. Furthermore, we believe that CMS can forgo the copy of applications provided by hospitals because the MGCRB's electronic module will facilitate CMS' verification of reclassification statuses during the wage index development process. Therefore, we are proposing to reduce burden for hospitals by eliminating the requirement to copy CMS. Specifically, we are proposing to revise § 412.256(a)(1) to delete the requirement that an electronic copy of the application be sent to CMS, so that this section would specify that an application must be submitted to the MGCRB according to the method prescribed by the MGCRB.

c. Proposed Revision To Clarify Criteria for a Hospital Seeking Reclassification to Another Rural Area or Urban Area

Section 412.230(a)(4) of our regulations currently specifies that the rounding of numbers to meet certain mileage or qualifying percentage standards is not permitted when an individual hospital seeks wage index reclassification through the MGCRB. In this section, the regulation specifically cites paragraphs (b)(1), (b)(2), (d)(1)(iii), and (d)(1)(iv)(A) and (B). The qualifying percentage standards included in these paragraphs have been periodically updated, and additional paragraphs have been added in § 412.230 to reflect these changes. Specifically, paragraphs (d)(1)(iv)(C), (D), and (E) have been added to § 412.230 to reflect changes in the percentage standards implemented in FY 2002, FY 2010, and FY 2011, respectively. Although we have continued to apply the policy set forth at § 412.230(a)(4) to the updated percentage standards set forth in paragraphs (d)(1)(iv)(C), (D), and (E) in § 412.230, conforming changes to § 412.230(a)(4) were not made to reflect these new paragraphs. This oversight has caused some confusion. Therefore, we are proposing to revise § 412.230(a)(4) to clarify that the policy prohibiting the rounding of qualifying percentage standards applies to paragraphs (d)(1)(iv)(C), (D), and (E) in § 412.230. Specifically, we are proposing to remove specific references to paragraphs (d)(1)(iv)(A) and (B) and instead cite paragraph (d)(1)(iv) as a more general reference to the specific standards.

3. Redesignations Under Section 1886(d)(8)(B) of the Act

a. Lugar Status Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the out-migration adjustment. In addition, in that rule, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of publication of the proposed rule for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov.* In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate ''Lugar'' status may be sent to

wageindex@cms.hhs.gov. To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests.

b. Clarification Regarding Accepting the Out-Migration Adjustment When the Outmigration Adjustment Changes After Reclassification

Section 1886(d)(8)(B) of the Act provides that for purposes a reclassification under this subsection, the Secretary shall treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute if certain criteria are met. Rural hospitals in these counties are commonly known as ''Lugar'' hospitals. This statutory provision specifies that Lugar status is mandatory (not optional) if the statutory criteria are met. However, as discussed in the FY 2012 IPPS/LTCH PPS proposed and final rules (76 FR 25885 through 25886 and 51599), Lugar hospitals located in counties that qualify for the out-migration adjustment are required to waive their Lugar urban status in its entirety in order to receive the out-migration adjustment. We stated our belief that this represents one permissible reading of the statute, given that section 1886(d)(13)(G) of the Act states that a hospital in a county that has an out-migration adjustment and that has not waived that adjustment under section 1886(d)(13)(F) of the Act is not eligible for reclassification under section 1886(d)(8) or (10) of the Act. Therefore, a hospital may opt to receive either its county's out-migration adjustment or the wage index determined by its Lugar reclassification.

We have become aware of a potential issue with the current election process that requires further clarification. As discussed in the following section, the out-migration adjustment is calculated to provide a positive adjustment to the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index. When a county is determined to qualify for an out-migration adjustment, the final adjustment value is determined in accordance with section 1886(d)(13)(D) of the Act and is fixed by statute for a 3-year period under section 1886(d)(13)(F) of the Act. CMS performs an annual analysis to evaluate all counties without current out-migration adjustment values assigned, including counties where the out-migration adjustment value will be expiring after a 3-year period. Initial out-migration adjustment values are published in Table 4 associated with the IPPS proposed and final rules (which are available via the internet on the CMS website). Due to various factors, including hospitals withdrawing or terminating MGCRB reclassifications, obtaining § 412.103 rural reclassifications, or corrections to hospital wage data, the amount of newly proposed (1st year) out-migration adjustment values may fluctuate between the proposed rule and the final rule (and subsequent correction notices). These fluctuations are typically minimal. However, in certain circumstances, after processing varying forms of reclassification, wage index values may change so that a county would no longer qualify for an out-migration adjustment. In particular, when changes in wage index reclassification status alter the State rural floor so that multiple CBSAs would be assigned the same wage index value, an out-migration adjustment may no longer be indicated for a county as there would be little, if any, differential in nearby wage index values. This can lead to a situation where a hospital has opted to receive a non-existent out-migration adjustment. We believe this situation is not compatible with longstanding CMS policy preventing a hospital from waiving its deemed urban Lugar status outside the prescribed out-migration adjustment election process described above. Section 1886(d)(13)(G) of the Act specifies that a hospital in a county that has a wage index increase under section 1886(d)(13)(F) of the Act (the out-migration adjustment) and that has not waived such increase under section 1886(d)(13)(F) of the Act is not eligible for reclassification under section 1886(d)(8) or (10) of the Act during that period. If there is no out-migration adjustment available to provide a wage index increase, the fact pattern for which CMS established the process for a hospital to opt to receive a county out-migration adjustment in lieu of its ''Lugar'' reclassification no longer applies, and the hospital must be assigned its deemed urban status. Therefore, we are clarifying that, in circumstances where an eligible hospital elects to receive the out-migration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located would no longer qualify for an out-migration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital's request to accept the out-migration adjustment would be denied, and the hospital would be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. Final rule wage index values would be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section 1886(d)(8)(B) of the Act, it would be ineligible to receive the county out-migration adjustment under section 1886(d)(13)(G) of the Act. Because the out-migration adjustment, once finalized, is locked for a 3-year period under section 1886(d)(13)(F) of the Act, the hospital would be eligible to accept its out-migration adjustment in either the second or third year.

c. Proposed Change to Lugar County Assignments

Section 1886(d)(8)(B) of the Act establishes a wage index reclassification process by which the Secretary is required to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban metropolitan statistical area (MSA), or core based statistical area (CBSA), to which the greatest number of workers in the county commute if certain criteria are met. Rural hospitals in these counties are known as ''Lugar'' hospitals and the counties themselves are often referred to as ''Lugar'' counties. These Lugar counties are not located in any urban area, but are adjacent to two or more urban CBSAs. In determining whether a county qualifies as a Lugar county, sections 1886(d)(8)(B)(i) and (ii) of the Act require us to use the standards for designating MSAs published in the **Federal Register** by OMB based on the most recent available decennial population data. Based on OMB definitions (75 FR 37246 through 37252), a CBSA is composed of ''central'' counties and ''outlying'' counties. While ''central'' counties meet certain population density requirements and other urban characteristics, a county qualifies as an ''outlying'' county of a CBSA if it meets one of the following commuting requirements: (a) At least 25 percent of the workers living in the county work in the central county or counties of the CBSA; or (b) at least 25 percent of the employment in the county is accounted for by workers who reside in the central county or counties

of the CBSA. Given the OMB standards above, when a county is located between two or more urban centers, these ''central'' county commuting patterns may be split between two or more CBSAs, and the 25-percent thresholds to qualify as an outlying county for any single CBSA may not be met. In such situations, the county would be considered rural according to CMS, based on the OMB definitions above, as it would not be part of an urban CBSA. Section 1886(d)(8)(B) of the Act addresses this issue where a county would have qualified as an outlying urban county if all its central county commuting data to adjacent urban CBSAs were combined. Specifically, section 1886(d)(8)(B)(i) of the Act requires CMS to consider a rural county to be part of an adjacent CBSA if the rural county would otherwise be considered part of an urban area under the OMB standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous MSAs. Section 1886(d)(8)(B)(i) further requires CMS to assign these Lugar counties to the CBSA to which the greatest number of workers in the county commute. Since the implementation of section 1886(d)(8)(B) of the Act for discharges occurring after October 1, 1988, CMS' policy has been that, once a county qualifies as Lugar, the proper methodology for determining the CBSA to which the greatest number of workers in the county commute should be based on the same OMB dataset used to determine whether a county qualifies as an ''outlying'' county of a CBSA. These data are a summary of commuting patterns between the non-central county being evaluated and the ''central'' county or counties of an urban metropolitan area (without taking into account outlying counties). Section 1886(d)(8)(B) of the Act clearly instructs CMS to use the OMB criteria for determining ''outlying'' counties when determining the list of qualifying Lugar counties. These criteria are limited to assessing commuting patterns to and from central counties. Further, we do not believe the statute requires that CMS perform an additional and separate community analysis, taking into account outlying counties, to determine to which CBSA a Lugar county should be assigned. When CMS updated the OMB labor market delineations based on 2010 decennial census in FY 2015, we were made aware that a hospital in Henderson County, TX (a Lugar county) disagreed with CMS' interpretation of the statute. In particular, the hospital stated that section 1886(d)(8)(B)(i) of the Act requires that CMS assign a qualified Lugar county to ''the urban metropolitan statistical area to which the greatest number of workers in the county commute,'' and that this instruction does not distinguish between an urban CBSA's central counties and outlying counties. The hospital claimed that the assignment of a Lugar county to a CBSA should not be based solely on commuting data and commuting patterns to and from the central county or counties of a CBSA, but should consider outlying counties as well.

After consideration of this matter, we continue to believe that CMS' methodology is a reasonable interpretation of the statute. However, upon further consideration and analysis, we have determined that the Henderson, TX hospital's interpretation of section 1886(d)(8)(B) of the Act is a reasonable alternative. After reanalyzing the commuting data used when developing the FY 2015 IPPS/LTCH PPS final rule (the American Community Survey commuting data for 2006–2010), we identified 10 instances where a rural county would have been assigned to a different CBSA if we had considered outlying counties in our analysis of the urban metropolitan statistical area to which the greatest number of workers in the county commute, as shown in the table below.

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Changes to Lugar County CBSAs When Including Outlying Counties in Out-Commuting Analysis

Lugar County Name	Lugar County State	FIPS County Code	Current Lugar CBSA	Current CBSA Name	Proposed Lugar CBSA	Proposed CBSA Name
Cleburne	AL	01029	11500	Anniston-Oxford-Jacksonville, AL	12060	Atlanta-Sandy Springs-Roswell, GA
Talladega	AL	01121	11500	Anniston-Oxford-Jacksonville, AL	13820	Birmingham-Hoover, AL
Polk	GA	13233	40660	Rome, GA	12060	Atlanta-Sandy Springs-Roswell, GA
Pearl River	MS	28109	25060	Gulfport-Biloxi-Pascagoula, MS	35380	New Orleans-Metairie, LA
Champaign	OH	39021	44220	Springfield, OH	18140	Columbus, OH
Susquehanna	PA	42115	13780	Binghamton, NY	42540	Scranton--Wilkes-Barre--Hazleton, PA
Lee	SC	45061	44940	Sumter, SC	17900	Columbia, SC
Grimes	TX	48185	17780	College Station-Bryan, TX	26420	Houston-The Woodlands-Sugar Land, TX
Henderson	TX	48213	46340	Tyler, TX	19124	Dallas-Plano-Irving, TX
Madison	VA	51113	16820	Charlottesville, VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV

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Of these 10 counties, currently only 3 counties (Talladega, AL, Pearl River, MS, and Henderson, TX) contain IPPS hospitals (4 hospitals in total). When including ''outlying'' counties in the commuting analysis, the analysis suggests that generally (but not always) the revised CBSA assignment would be to a larger CBSA, which would be expected as larger CBSAs generally include a greater number of ''outlying'' counties. After further consideration of this issue, we believe that inclusion of outlying counties in the commuting analysis for purposes of assigning counties that qualify as Lugar counties (the second step of the Lugar analysis),

although not unambiguously required by statute, is a reasonable, and arguably more natural, reading of the language in section 1886(d)(8)(B)(i) of the Act. Accordingly, we are proposing to modify the assigned CBSA for the 10 Lugar counties specified in the table above for FY 2020. We also plan to fully reevaluate this proposed policy and underlying methodologies, if finalized, when CMS updates Lugar county assignments, which typically occurs after OMB labor market delineations are updated in response to the next decennial census.

J. Proposed Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at that time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in the FYs 2016, 2017, 2018, and 2019 IPPS/LTCH PPS final rules (80 FR 49501, 81 FR 56930, 82 FR 38150, and 83 FR 41384, respectively), the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment were applicable for FYs 2016 through 2019, and we are proposing to use them again for FY 2020. We have applied the same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2020. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2020, the out-migration adjustment will continue to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-year) Microdata. For future fiscal years, we may consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate. For FY 2020, we are not proposing any changes to the methodology or data source that we used for FY 2016 (81 FR 25071). (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).)

Table 2 associated with this proposed rule (which is available via the internet on the CMS website) includes the proposed out-migration adjustments for the FY 2020 wage index. In addition, as discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20367), we have added a Table 4, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act.'' For this proposed rule, Table 4 consists of the following: A list of counties that would be eligible for the out-migration adjustment for FY 2020 identified by FIPS county code, the proposed FY 2020 out-migration adjustment, and the number of years the adjustment would be in effect. We believe this table makes this information more transparent and provides the public with easier access to this information. We note that we intend to make the information available annually via Table 4 associated with the IPPS/LTCH PPS proposed and final rules, and are including it among the tables associated with this FY 2020 IPPS/LTCH PPS proposed rule that are available via the internet on the CMS website.

K. Reclassification From Urban to Rural Under Section 1886(d)(8)(E) of the Act, Implemented at 42 CFR 412.103

1. Application for Rural Status and Lock-In Date

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals.

Hospitals must meet the criteria to be reclassified from urban to rural status under § 412.103, as well as fulfill the requirements for the application process. There may be one or more reasons that a hospital applies for the urban to rural reclassification, and the timeframe that a hospital submits an application is often dependent on those reason(s). Because the wage index is part of the methodology for determining the prospective payments to hospitals for each fiscal year, we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931) that we believed there should be a definitive timeframe within which a hospital should apply for rural status in order for the reclassification to be reflected in the next Federal fiscal year's wage data used for setting payment rates.

Therefore, after notice of proposed rulemaking and consideration of public comments, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931 through 56932), we revised § 412.103(b) by

adding paragraph (6) to specify that, in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital's filing date (the lock-in date) must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41384 through 41386), we changed the lock-in date to provide for additional time in the ratesetting process and to match the lock-in date with another existing deadline, the usual public comment deadline for the IPPS proposed rule. We revised § 412.103(b)(6) to specify that, in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital's application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103 no later than 60 days after the public display date at the Office of the Federal Register of the IPPS proposed rule for the next Federal fiscal year.

The lock-in date does not affect the timing of payment changes occurring at the hospital-specific level as a result of reclassification from urban to rural under § 412.103. As we discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41385 through 41386), this lock-in date also does not change the current regulation that allows hospitals that qualify under § 412.103(a) to request, at any time during a cost reporting period, to reclassify from urban to rural. A hospital's rural status and claims payment reflecting its rural status continue to be effective on the filing date of its reclassification application, which is the date the CMS Regional Office receives the application, in accordance with § 412.103(d). The hospital's IPPS claims will be paid reflecting its rural status beginning on the filing date (the effective date) of the reclassification, regardless of when the hospital applies.

2. Proposed Change to the Regulations To Allow for Electronic Submission of Applications for Reclassification From Urban to Rural Status

The application requirements at § 412.103(b)(3) for reclassification from urban to rural status currently state that an application must be mailed to the CMS Regional Office by the requesting hospital and may not be submitted by facsimile or other electronic means. We believe that this policy is outdated and overly restrictive. In the interest of burden reduction and to promote ease of application, in this proposed rule, we are proposing to eliminate the restriction on submitting an application by facsimile or other electronic means so that hospitals may also submit applications to the CMS Regional Office electronically. Accordingly, we are proposing to revise § 412.103(b)(3) to allow a requesting hospital to submit an application to the CMS Regional Office by mail or by facsimile or other electronic means.

3. Proposed Changes to Cancellation Requirements for Rural Reclassifications

Under current regulations at § 412.103(g)(1), hospitals, other than those hospitals that are rural referral centers (RRCs), may cancel a rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days before the end of its current cost reporting period, effective beginning with the next full cost reporting period. Under the current regulations at § 412.103(g)(2), a hospital that was classified as an RRC under § 412.96 based on rural reclassification under § 412.103 may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of the Federal fiscal year and after being paid as rural for at least one 12-month cost reporting period. The RRC's cancellation of a § 412.103 rural reclassification is not effective until it has been paid as rural for at least one 12-month cost reporting period, and not until the beginning of the Federal fiscal year following both the request for cancellation and the 12-month cost reporting period.

In this proposed rule, we are proposing to revise the rural reclassification cancellation requirements at § 412.103(g) for hospitals classified as RRCs. Currently, § 412.103(g)(2) requires that, for a hospital that has been classified as an RRC based on rural reclassification under § 412.103, cancellation of a § 412.103 rural reclassification is not effective until the hospital that is classified as an RRC has been paid as rural for at least one 12-month cost reporting period, and not until the beginning of the Federal fiscal year following both the request for cancellation and the 12-month cost reporting period. We stated in the FY 2008 IPPS final rule (72 FR 47371 through 47373) that the goal of creating this minimum time period was to disincentivize hospitals from receiving a rural redesignation, obtaining RRC status to take advantage of special MGCRB reclassification rules, and then terminating their rural status. However, as suggested by a commenter in response to the April 22, 2016 interim final rule with comment period (81 FR 56926), this disincentive is no longer necessary now that hospitals can have simultaneous MGCRB and § 412.103 reclassifications. Accordingly, in this proposed rule, we are proposing to revise § 412.103(g)(2)(iii) to specify that the provisions set forth at § 412.103(g)(2)(i) and (ii) are effective for all written requests submitted by hospitals on or after October 1, 2007 and before October 1, 2019 to cancel rural reclassifications. Therefore, the reclassification cancellation requirements specific to RRCs at § 412.103(g)(2) would no longer apply for cancellation requests submitted on or after October 1, 2019. In addition, as further discussed below, we are proposing to revise § 412.103(g) to include uniform reclassification cancellation requirements that would be applied to all hospitals effective for cancellation requests submitted on or after October 1, 2019.

As further discussed below, we are proposing to revise the regulations at § 412.103(g) to set forth uniform requirements applicable to all hospitals for cancelling rural reclassifications. Currently, for non-RRCs, the cancellation of rural status is effective beginning with the hospital's next cost reporting period. A hospital that has a § 412.103 rural reclassification and that does not have an additional MGCRB or ''Lugar'' reclassification is assigned the rural wage index value for its State. Because wage index values are determined and assigned to hospitals on a Federal fiscal year basis, when such an aforementioned hospital cancels its rural reclassification, the wage index value must be manually updated by the MAC to its appropriate urban wage index value. Because the end dates of cost reporting periods vary among hospitals, this process can be cumbersome and some cancellation requests may not be processed in time to be accurately reflected in the IPPS final rule appendix tables. Because there is no apparent advantage to continuing to link the rural reclassification cancellation date to a hospital's cost reporting period, we believe that, in the interests of reducing overall complexity and administrative burden, the cancellation of rural reclassification should be effective for all hospitals

beginning with the next Federal fiscal year (that is, the Federal fiscal year following the cancellation request). In addition, similar to the current requirements at § 412.103(g)(2), we believe it would be appropriate to require hospitals to request cancellation not less than 120 days prior to the end of a Federal fiscal year. We believe this proposed 120-day timeframe would provide hospitals adequate time to assess and review reclassification options, and provide CMS adequate time to incorporate the cancellation in the wage index development process. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41384 through 41386), we finalized a lock-in date for a new rural reclassification to be approved in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year. We considered using this deadline, which is 60 days after the public display date at the Office of the Federal Register of the IPPS proposed rule for the next Federal fiscal year, as the deadline to submit cancellation requests effective for the next Federal fiscal year as well. While we see certain advantages with aligning various wage index deadlines to the same date, based on the public display date of the proposed rule, we believe the proposed deadline of not less than 120 days prior to the end of the Federal fiscal year would give hospitals adequate time to assess and review reclassification options, and CMS adequate time to incorporate the cancellation in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year. In addition, this proposed 120-day deadline is already familiar to many hospitals because it is similar to the current deadline under § 412.103(g)(2), and therefore, we believe implementation of the proposed deadline may pose less of a burden overall for many hospitals. For these reasons, we are proposing to add paragraph (g)(3) to § 412.103 to specify that, for all written requests submitted by hospitals on or after October 1, 2019 to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of a Federal fiscal year, and the hospital's cancellation of the classification would be effective beginning with the next Federal fiscal year. In addition, we are proposing to add paragraph (g)(1)(iii) to § 412.103 to specify that the provisions of paragraphs (g)(1)(i) and (ii) of § 412.103 are effective only for written requests submitted by hospitals before October 1, 2019 to cancel rural reclassification.

In addition, we are proposing to codify into regulations a longstanding CMS policy regarding canceling a § 412.103 reclassification when a hospital opts to accept and receives its county out-migration adjustment in lieu of its ''Lugar'' reclassification. As discussed in section III.I.3. of the preamble of this proposed rule, a hospital may opt to receive either its ''Lugar'' county reclassification established under section 1886(d)(8)(B) of the Act, or the county out-migration adjustment determined under section 1886(d)(13) of the Act. Such requests may be submitted to CMS by email to *wageindex@cms.hhs.gov* within 45 days of the public display date of the proposed rule for the next Federal fiscal year. We established this process because section 1886(d)(13)(G) of the Act prohibits a hospital from having both an out-migration wage index adjustment and reclassification under section 1886(d)(8) or (10) of the Act. Because § 412.103 reclassifications were established under section 1886(d)(8)(E) of the Act, a hospital cannot simultaneously have an out-migration adjustment and be reclassified as rural under § 412.103. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51600), we addressed a commenter's concern regarding timing issues for some hospitals that wish to receive their county out-migration adjustment, but would not have adequate time to also cancel their rural reclassification. In that rule, we stated that ''we will allow the act of waiving Lugar status for the out-migration adjustment to simultaneously waive the hospital's deemed urban status and cancel the hospital's acquired rural status, thus treating the hospital as a rural provider effective on October 1.'' While this policy modification was initially discussed in the FY 2012 IPPS/LTCH PPS final rule in the context of hospitals wishing to obtain or maintain sole community hospital (SCH) or Medicare-dependent hospital (MDH) status, its application has not been limited to current or potential SCHs or MDHs. We continue to believe this policy of automatically canceling rural reclassifications when a hospital waives its Lugar reclassification to receive its out-migration adjustment reduces overall burden on hospitals by not requiring them to file a separate rural reclassification cancellation request. We also believe this policy reduces overall complexity for CMS, avoiding the need to track and process multiple cancellation requests. Accordingly, we believe this policy should be codified in the regulations at § 412.103.

Therefore, we are proposing to add paragraph (g)(4) to § 412.103 to specify that a rural reclassification will be considered cancelled effective for the next Federal fiscal year when a hospital opts (by submitting a request to CMS within 45 days of the date of public display of the proposed rule for the next Federal fiscal year at the Office of the Federal Register in accordance with the procedure described in section III.I.3. of the preamble of this proposed rule) to accept and receives its county out-migration wage index adjustment determined under section 1886(d)(13) of the Act in lieu of its geographic reclassification described under section 1886(d)(8)(B) of the Act. If the hospital wishes to once again obtain a § 412.103 rural reclassification, it would have to reapply through the CMS Regional Office in accordance with § 412.103, and the hospital would once again be ineligible to receive its out-migration adjustment. We note that, in a case where a hospital reclassified as rural under § 412.103 wishes to receive its out-migration adjustment but does not qualify for a ''Lugar'' reclassification, the hospital would need to formally cancel its § 412.103 rural reclassification by written request to the CMS Regional Office within the timeframe specified at § 412.103. Finally, in order to address the scenario described in section III.I.3.b. of the preamble of this proposed rule, we note that, in proposed § 412.103(g)(4), we are providing that the hospital must not only opt to accept, but also *receive,* its county out-migration wage index adjustment to trigger cancellation of rural reclassification under that provision. In such cases where an out-migration adjustment is no longer applicable based on the wage index in the final rule, a hospital's rural reclassification remains in effect (unless otherwise cancelled by written request to the CMS Regional Office within the timeframe specified at § 412.103).

L. Process for Requests for Wage Index Data Corrections

1. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files and the preliminary CY 2016 occupational mix data files for the proposed FY 2020 wage index were made available on June 5, 2018 through the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-*

Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2020-Wage-Index-Home-Page.html.

On January 31, 2019, we posted a public use file (PUF) at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2020-Wage-Index-Home-Page.html* containing FY 2020 wage index data available as of January 30, 2019. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2015 through September 30, 2016; that is, FY 2016 wage data), a tab with the occupational mix data (which includes data from the CY 2016 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 31, 2019 wage data PUF, and a tab containing the CY 2016 occupational mix data of the hospitals deleted from the January 31, 2019 occupational mix PUF. In a memorandum dated January 18, 2019, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 31, 2019 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2020 Wage Index Timetable.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS website at: *http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html.*

In a memorandum dated April 20, 2018, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files and the CY 2016 occupational mix survey data files posted on May 18, 2018, and the process and timeframe for requesting revisions.

In a memorandum dated June 6, 2018, we corrected and reposted the preliminary wage file on our website because we realized that the PUF originally posted on May 18 2018 did not include new line items that were first included in cost reports for cost reporting periods beginning on or after October 1, 2015 (and will be used for the first time in the FY 2020 wage index). Specifically, the lines are: Worksheet S–3, Part II, lines 14.01 and 14.02, and 25.50, 25.51, 25.52, and 25.53; and Worksheet S–3, Part IV, lines 8.01, 8.02, 8.03. In the same memorandum, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the corrected and reposted preliminary wage index data files and the CY 2016 occupational mix survey data files posted on June 6, 2018, and the process and timeframe for requesting revisions.

If a hospital wished to request a change to its data as shown in the June 6, 2018 preliminary wage and occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC by September 4, 2018. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs. November 16, 2018 was the deadline for MACs to complete all desk reviews for hospital wage and occupational mix data and transmit revised Worksheet S–3 wage data and occupational mix data to CMS.

November 6, 2018 was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. Additional revisions made by the MACs were transmitted to CMS throughout January 2019. CMS published the wage index PUFs that included hospitals' revised wage index data on January 31, 2019. Hospitals had until February 15, 2019, to submit requests to the MACs to correct errors in the January 31, 2019 PUF due to CMS or MAC mishandling of the wage index data, or to revise desk review adjustments to their wage index data as included in the January 31, 2019 PUF. Hospitals also were required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 22, 2019. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) was April 4, 2019. Data that were incorrect in the preliminary or January 31, 2019 wage index data PUFs, but for which no correction request was received by the February 15, 2019 deadline, are not considered for correction at this stage. In addition, April 4, 2019 was the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified after the January 31, 2019 PUF and at least 14 calendar days prior to April 4, 2019 (that is, March 21, 2018), that do not arise from a hospital's request for revisions. We note that, as with previous years, for the proposed FY 2020 wage index, in accordance with the FY 2020 wage index timeline posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2020-Wage-Index-Home-Page.html,* the April appeals have to be sent via mail and email. We refer readers to the wage index timeline for complete details.

Hospitals are given the opportunity to examine Table 2 associated with this proposed rule, which is listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS-FY2020-IPPS-Proposed-Rule-Home-Page.html.* Table 2 contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2016 data used to construct the proposed FY 2020 wage index. We note that the proposed hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by early February 2019.

We plan to post the final wage index data PUFs in late April 2019 via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2020-Wage-Index-Home-Page.html.* The April 2019 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process previously described (the process for disputing revisions submitted to CMS by the MACs by March 21, 2019, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier).

After the release of the April 2019 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the

MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 21, 2018.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 31, 2019 wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2019 final wage index data PUFs, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC no later than May 30, 2019. May 30, 2019 is also the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified on or after 13 calendar days prior to April 4, 2019 (that is, March 22, 2019), and at least 14 calendar days prior to May 30, 2019 (that is, May 16, 2019), that do not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital is notified on or after 13 calendar days prior to May 30, 2019 (that is, May 17, 2019) may be appealed to the Provider Reimbursement Review Board (PRRB)). Similar to the April appeals, beginning with the FY 2015 wage index, in accordance with the FY 2020 wage index timeline posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2020-Wage-Index-Home-Page.html,* the May appeals must be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details.

Verified corrections to the wage index data received timely (that is, by May 30, 2019) by CMS and the MACs will be incorporated into the final FY 2020 wage index, which will be effective October 1, 2019.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2020 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision would be required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to requested changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals have access to the final wage index data PUFs by late April 2019, they have the opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2020 wage index by August 2019, and the implementation of the FY 2020 wage index on October 1, 2019. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 30, 2019, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 30, 2019 for the FY 2020 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 30, 2019 deadline for the FY 2020 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 30, 2019 deadline for the FY 2020 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data.

In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

2. Process for Data Corrections by CMS After the January 31 Public Use File (PUF)

The process set forth with the wage index timeline discussed in section III.L.1. of the preamble of this proposed rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data in order to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 31 PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data that may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). Furthermore, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension, CMS would correct that data error and the hospital's average hourly wage would likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 31 PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency to instances where CMS makes data corrections after the January 31 PUF, and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described earlier and in the FY 2020 Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

M. Proposed Labor-Related Share for the Proposed FY 2020 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-

related share resulted in a higher payment.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we rebased and revised the hospital market basket. We established a 2014-based IPPS hospital market basket to replace the FY 2010-based IPPS hospital market basket, effective October 1, 2017. Using the 2014-based IPPS market basket, we finalized a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2017. In addition, in FY 2018, we implemented this revised and rebased labor-related share in a budget neutral manner (82 FR 38522). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41389 and 41390), for FY 2019, we continued to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2018.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. In this proposed rule, for FY 2020, we are not proposing to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, employee benefits, professional fees: Labor-related, administrative and facilities support services, installation, maintenance, and repair services, and all other labor-related services. Therefore, for FY 2020, we are proposing to continue to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2019.

As discussed in section IV.B. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2020, we are not proposing a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2020 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflect the proposed national labor-related share, which is also applicable to Puerto Rico hospitals. For FY 2020, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2020, we are proposing to apply the wage index to a proposed labor-related share of 68.3 percent of the national standardized amount.

N. Proposals To Address Wage Index Disparities Between High and Low Wage Index Hospitals

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20372), we invited the public to submit further comments, suggestions, and recommendations for regulatory and policy changes to the Medicare wage index. Many of the responses received from this request for information (RFI) reflect a common concern that the current wage index system perpetuates and exacerbates the disparities between high and low wage index hospitals. Many respondents also expressed concern that the calculation of the rural floor has allowed a limited number of States to manipulate the wage index system to achieve higher wages for many urban hospitals in those states at the expense of hospitals in other states, which also contributes to wage index disparities.

To help mitigate these wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications under 42 CFR 412.103 in the calculation of the rural floor, we are proposing to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and decreasing the wage index values for certain hospitals with high wage index values to maintain budget neutrality, and changing the calculation of the rural floor, as further discussed below. We also are proposing a transition for hospitals experiencing significant decreases in their wage index values as a result of our proposed wage index policies. We discuss these proposed changes to the wage index in more detail below.

1. Prior Rulemaking Public Comments

As described in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20372 through 20377), there have been numerous studies, analyses, and reports on ways to revise the Medicare wage index. In public comments received on prior rulemakings for FYs 2009, 2010, and 2011, many commenters argued that the current labor market definitions and wage data sources used by CMS, in many instances, are not reflective of the true cost of labor for any given hospital or are inappropriate to use for this purpose because of, for example, the resulting payment disparities, or both. For our responses to public comments received on the FY 2009 IPPS/LTCH PPS proposed rule, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48563 through 48567); for responses to public comments on the FY 2010 IPPS/LTCH PPS proposed rule, we refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43824 through 43826); and for responses to public comments on the FY 2011 IPPS/LTCH PPS proposed rule, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50157 through 50160). The public comments on these proposed rules are available at *www.regulations.gov* under file numbers CMS–1390–P, CMS–1406–P, and CMS–1498–P, respectively.

In the FY 2019 IPPS/LTCH proposed rule, we invited the public to submit further comments, suggestions, and recommendations for regulatory and policy changes to the Medicare wage index. We requested the public to submit appropriate supporting data and specific recommendations in their comments. We also welcomed analysis

regarding CMS' authority for our consideration. We received many comments, many of which addressed wage index disparities between high and low wage index hospitals. The following is a summary of the comments we received on the wage index disparity issue. We note that we also received comments regarding other aspects of the wage index system, including current labor market areas, MGCRB reclassifications, use of alternative data, and the use of the hospital wage index by nonhospital providers. We will continue to consider those comments for potential future rulemaking.

2. Public Comments on Wage Index Disparities in Response to the Request for Information in the FY 2019 IPPS/LTCH PPS Proposed Rule

One of the concerns regarding the wage index system expressed by hospitals in low wage index areas is the disparity in wage index values between high and low wage index areas. The following comment, received in response to the request for information in the FY 2019 IPPS/LTCH PPS proposed rule, is a typical comment in this regard:

''The most significant issue with the current system can be traced to the data sources used to calculate the wage index. Relying exclusively on hospital cost reports as the source to calculate the wage index allows hospitals in States with significantly higher wage indexes to maintain and improve their favorable position in the current system by setting higher than market value wages for their employees. The higher wage hospitals can, by virtue of higher Medicare payments, afford to pay wages that allow them to continue as a high wage index State. Low wage index States . . . cannot afford to pay wages that would allow their hospitals to climb back toward the median wage index. Over time this condition of circularity has increased the gap between the wage indexes of the high and low wage States to a much larger degree than what the wage index was initially designed to address, the difference in labor markets across the country for comparable services.''

For discussion purposes, we will refer to this situation as the ''downward spiral,'' as this term has been used by some stakeholders to describe this issue. Some respondents stated that the disparity between the higher and lower wage index areas continues to grow and suggested that the problem is, in large part, due to providers in low wage index areas having difficulty keeping pace with competitive labor costs and having to reduce expenses in other areas to make up for it. Some respondents indicated that the downward spiral faced by hospitals in low wage index areas was the most important wage index issue facing the system and it needed to be addressed quickly.

Some respondents recommended that CMS create a wage index floor for low wage hospitals, and that, in order to maintain budget neutrality, CMS reduce the wage index values for high wage hospitals through the creation of wage index ceiling.

Some respondents also indicated that the current wage index methodology encourages misuse and opportunist gaming, especially in the area of urban to rural reclassifications and the rural floor. According to these respondents, under current policies, providers in some urban areas are able to reclassify to a rural area and substantially raise the rural floor for an entire State. Several respondents suggested that this is inconsistent with the intent of the rural floor policy, which is to protect vulnerable urban hospitals, and that the policy was not intended to allow urban hospitals to artificially inflate the rural floor through urban to rural reclassification. These respondents indicated that, because the rural floor policy is budget neutral nationally, all providers throughout the country that do not benefit from the rural floor policy have their payments lowered due to this misuse and opportunistic gaming. These respondents stressed that this further contributes to financial distress of hospitals in low wage index areas.

Some respondents stated that CMS has the regulatory authority to determine how it calculates the rural floor. They stated that the calculation should mirror the spirit and intent of law by only considering the geographically rural providers in a State when calculating a rural floor. According to these respondents, CMS should consider changing the existing calculation to include only the geographically rural providers when calculating the rural floor for a State in order to ensure that existing regulatory policy around the rural floor calculation meets the intent of law and does not harm vulnerable providers the law intended to protect.

Other commenters were not critical in their comments regarding wage index disparities. The following is a typical comment arguing that the reflection of such disparities in the wage index is appropriate:

''CMS has requested comments on wage index disparities, but we urge the agency to continue to recognize that as long as there are 'disparities' in the cost of labor and cost of living between different parts of the country, there will and should always be wage index 'disparities'. The area wage index is intended to recognize differences in resource use across types and location of hospitals. In a quest to smooth out so-called 'disparities', we urge CMS to continue to adequately account for these resource differences in its payment systems.''

Some commenters indicated that further analysis and study are needed. The following comment is a typical comment expressing this view:

''The area wage index is intended to recognize differences in resource use across types and location of hospitals. If these resource differences are not adequately accounted for by Medicare payment adjustments, hospitals are either inappropriately rewarded or put under fiscal pressure. Taking this into account, hospitals have repeatedly expressed concern that the wage index is greatly flawed in many respects, including its accuracy, volatility, circularity, and substantial reclassifications and exceptions. Members of Congress and Medicare officials also have voiced concerns with the present system. While a consensus solution to the wage index's shortcomings has not yet been developed, further analysis of alternatives is needed to identify approaches that promote payment adjustments that are accurate, fair, and effective.''

As noted earlier, we also received comments regarding other aspects of the wage index system. We will continue to consider those responses for potential future rulemaking. We encourage interested members of the public to review all the comments on the wage index received in response to the request for information in their entirety, which are available at *www.regulations.gov* under file number CMS–1694–P.

3. Proposals To Address Wage Index Disparities

a. Providing an Opportunity for Low Wage Index Hospitals To Increase Employee Compensation

As CMS and other entities have stated in the past, comprehensive wage index reform would require both statutory and regulatory changes, and could require new data sources. Notwithstanding the challenges associated with comprehensive wage index reform, we agree with respondents to the request for information who indicated that some current wage index policies create barriers to hospitals with low wage index values from being able to increase employee compensation due to the lag

between when hospitals increase the compensation and when those increases are reflected in the calculation of the wage index. (We note that this lag results from the fact that the wage index calculations rely on historical data.) We also agree that addressing this systemic issue does not need to wait for comprehensive wage index reform given the growing disparities between low and high wage index hospitals, including rural hospitals that may be in financial distress and facing potential closure. Therefore, in response to these concerns, we are proposing a policy that would provide certain low wage index hospitals with an opportunity to increase employee compensation without the usual lag in those increases being reflected in the calculation of the wage index.

In general terms, as discussed further below, we are proposing to increase the wage index values for hospitals with a wage index value in the lowest quartile of the wage index values across all hospitals. Quartiles are a common way to divide a distribution, and therefore we believe it is appropriate to divide the wage indexes into quartiles for this purpose. For example, the interquartile range is a common measure of variability based on dividing data into quartiles. Furthermore, quartiles are used to divide distributions for other purposes under the Medicare program. For example, when determining Medicare Advantage benchmarks, excluding quality bonuses, counties are organized into quartiles based on their Medicare fee-for-service (FFS) spending. Also, Congress chose the worst performing quartile of hospitals for the Hospital-Acquired Condition Reduction Program penalty. (We refer readers to section IV.J. of the preamble of this proposed rule for a discussion of the Hospital-Acquired Condition Reduction Program.) Having determined that quartiles are a reasonable method of dividing the distribution of hospitals' wage index values, we believe that identifying hospitals in the lowest quartile as low wage index hospitals, hospitals in the second and third ''middle'' quartiles as hospitals with wages index values that are neither low nor high, and hospitals in the highest quartile as hospitals with high wage index values, is then a reasonable method of determining low wage index and high wage index hospitals for purposes of our proposals (discussed below) addressing wage index disparities. While we acknowledge that there is no set standard for identifying hospitals as having low or high wage index values, we believe our proposed quartile approach is reasonable for this purpose, given that, as discussed above, quartiles are a common way to divide distributions, and this proposed approach is consistent with approaches used in other areas of the Medicare program.

Based on the data for this proposed rule, for FY 2020, the 25th percentile wage index value across all hospitals is 0.8482. If this policy is adopted in the final rule, this number would be updated in the final rule based on the final wage index values.

Under our proposed methodology, we are proposing to increase the wage index for hospitals with a wage index value below the 25th percentile wage index. The proposed increase in the wage index for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. For example, assume the otherwise applicable final FY 2020 wage index value for a geographically rural hospital in Alabama is 0.6663, and the 25th percentile wage index value for FY 2020 is 0.8482. Half the difference between the otherwise applicable wage index value and the 25th percentile wage index value is 0.0910 (that is, (0.8482 − 0.6663)/2). Under our proposal, the FY 2020 wage index value for such a hospital would be 0.7573 (that is, 0.6663 + 0.0910).

Some respondents to the request for information indicated that CMS should establish a wage index floor for hospitals with low wage index values. However, we believe that it is important to preserve the rank order of the wage index values under the current policy and, therefore, are proposing to increase the wage index for the low-wage index hospitals described above by half the difference between the otherwise applicable final wage index value and the 25th percentile wage index value. We believe the rank order generally reflects meaningful distinctions between the employee compensation costs faced by hospitals in different geographic areas. Although wage index value differences between areas may be artificially magnified by the current wage index policies, we do not believe those differences are nonexistent. For example, if we were to instead create a floor to address the lag issue discussed above, it does not seem likely that hospitals in Puerto Rico and Alabama would have the same wage index value after hospitals in both areas have had the opportunity increase their employee compensation costs. We believe a distinction between their wage index values would remain because hospitals in these areas face different employee compensation costs in their respective labor market areas.

We are proposing that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. For the FY 2020 wage index, we are proposing to use data from the FY 2016 cost reports. Four years is the minimum time before increases in employee compensation included in the Medicare cost report could be reflected in the wage index data, and additional time may be necessary. We intend to revisit the issue of the duration of the policy in future rulemaking as we gain experience under the policy if adopted.

b. Budget Neutrality for Providing an Opportunity for Low Wage Index Hospitals To Increase Employee Compensation

As noted earlier, in response to the request for information on wage index disparities in the FY 2019 IPPS/LTCH PPS proposed rule, some respondents recommended that CMS create a wage index floor for low wage index hospitals, and that, in order to maintain budget neutrality, CMS reduce the wage index values for high wage index hospitals through the creation of wage index ceiling.

While we do not believe it would be appropriate to create a wage index floor or a wage index ceiling as suggested in the comment summarized above, we believe the suggestion that we provide a mechanism to increase the wage index of low wage index hospitals (as we have proposed in section III.N.3.a. of the preamble of this proposed rule) while maintaining budget neutrality for that increase through an adjustment to the wage index of high wage index hospitals has two key merits. First, by compressing the wage index for hospitals on the high and low ends, that is, those hospitals with a low wage index and those hospitals with a high wage index, such a methodology increases the impact on existing wage index disparities more than by simply addressing one end. Second, such a methodology ensures those hospitals in the middle, that is, those hospitals whose wage index is not considered high or low, do not have their wage index values affected by this proposed policy. Thus, given the growing disparities between low wage index hospitals and high wage index hospitals, consistent with the comment summarized above, we believe it would

be appropriate to maintain budget neutrality for the low wage index policy proposed in section III.N.3.a. of the preamble of this proposed rule by adjusting the wage index for high wage index hospitals.

As discussed earlier, we believe it is important to preserve the rank order of wage index values because the rank order generally reflects meaningful distinctions between the employee compensation costs faced by hospitals in different geographic areas. Although wage index value differences between areas (including areas with high wage index hospitals) may be artificially magnified by the current wage index policies, we do not believe those differences are nonexistent, and therefore, we do not believe it would be appropriate to set a wage index ceiling or floor. Accordingly, in order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile under our proposal in section III.N.3.a. of the preamble of this proposed rule, we are proposing to decrease the wage index values for hospitals with high wage index values, but preserve the rank order among those values, as further discussed below.

As discussed in section III.N.3.a. of the preamble of this proposed rule, we believe it is reasonable to divide all hospitals into quartiles based on their wage index value whereby we identify hospitals in the lowest quartile as low wage index hospitals, hospitals in the second and third ''middle'' quartiles as hospitals with wage index values that are neither high nor low, and hospitals in the highest quartile as hospitals with high wage index values. We believe our proposed quartile approach is reasonable for this purpose, given that, as discussed above, quartiles are a common way to divide distributions, and this proposed approach is consistent with approaches used in other areas of the Medicare program. Therefore, we are proposing to identify high wage index hospitals as hospitals in the highest quartile, and in the budget neutrality discussion that follows, we refer to hospitals with wage index values above the 75th percentile wage index value across all hospitals for a fiscal year as ''high wage index hospitals.''

To ensure our proposal in section III.N.3.a. of the preamble of this proposed rule is budget neutral, we are proposing to reduce the wage index values for high wage index hospitals using a methodology analogous to the methodology used to increase the wage index values for low wage index hospitals described in section III.N.3.a. of the preamble of this proposed rule; that is, we are proposing to decrease the wage index values for high wage index hospitals by a uniform factor of the distance between the hospital's otherwise applicable wage index and the 75th percentile wage index value for a fiscal year across all hospitals. As described below, the proposed budget neutrality adjustment factor is 3.4 percent for FY 2020.

In calculating the proposed budget neutrality adjustment factor for our proposal in section III.N.3.a. of the preamble of this proposed rule, we would first examine the distance between the wage index values for high wage index hospitals and the 75th percentile wage index value across all hospitals for a fiscal year. Based on the data for this proposed rule, the 75th percentile wage index value is 1.0351. Therefore, for example, if high wage index Hospital A had an otherwise applicable wage index value of 1.7351, the distance between that hospital's wage index value and the 75th percentile is 0.7000 (that is, 1.7351 − 1.0351). If high wage index Hospital B had an otherwise applicable wage index value of 1.2351, the distance between that hospital's wage index value and the 75th percentile is 0.2000 (that is, 1.2351 − 1.0351).

We would next estimate the uniform multiplicative budget neutrality factor needed to reduce those distances for all high wage index hospitals so that the estimated decreased aggregate payments to high wage index hospitals offset the estimated increased aggregate payments to low wage index hospitals under our proposed policy in section III.N.3.a. of the preamble of this proposed rule. Based on the data for this proposed rule, we estimate this factor is 3.4 percent for FY 2020.

Therefore, in the examples we provided earlier, the distance between Hospital A's wage index value and the 75th percentile would be reduced by 0.0238 (that is, the prior distance of 0.7000 * 0.034), and therefore the wage index for Hospital A after application of the proposed budget neutrality adjustment would be 1.7113 (that is, 1.7351 − 0.0238). The distance between Hospital B's wage index value and the 75th percentile would be reduced by 0.0068 (that is, the prior distance of 0.2000 * 0.034), and therefore the wage index for Hospital B after application of the proposed budget neutrality adjustment would be 1.2283 (that is, 1.2351 − 0.0068).

We believe we have authority to implement our lowest quartile wage index proposal in section III.N.3.a. of the preamble of this proposed rule and our budget neutrality proposal in this section III.N.3.b. of the preamble of this proposed rule under section 1886(d)(3)(E) of the Act (which gives the Secretary broad authority to adjust for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, and requires those adjustments to be budget neutral), and under our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act.

c. Preventing Inappropriate Payment Increases Due to Rural Reclassifications Under the Provisions of 42 CFR 412.103

We also agree with respondents to the request for information who indicated that another contributing systemic factor to wage index disparities is the rural floor. As discussed in section III.G.1. of the preamble of this proposed rule, section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor.

The rural floor policy was addressed by the Office of the Inspector General (OIG) in its recent November 2018 report, ''Significant Vulnerabilities Exist in the Hospital Wage Index System for Medicare Payment'' (A–01–17–00500), which is available on the OIG website at: *https://oig.hhs.gov/oas/reports/region1/11700500.pdf.* The OIG stated (we note that the footnote references included here were in the original document but are not carried here):

''The stated legislative intent of the rural floor was to correct the 'anomaly' of 'some urban hospitals being paid less than the average rural hospital in their States.' [9] However, MedPAC, an independent congressional advisory board, has since stated that it is 'not aware of any empirical support for this policy,[10] and that the policy is built on the false assumption that hospital wage rates in all urban labor markets in a State are always higher than the average hospital wage rate in rural areas of that State.[11] ''

As one simplified example for purposes of illustrating the rural floor policy, assume that the rural wage index for a State is 1.1000. Therefore, under current policy, the rural floor for that State would be 1.1000. Any urban hospital with a wage index value below

1.1000 in that State would have its wage index value raised to 1.1000. The additional Medicare payments to those urban hospitals in that State increase the national budget neutrality adjustment for the rural floor provision.

For a real world example of the impact of the rural floor policy, we point to FY 2018, in which 366 urban hospitals benefitted from the rural floor. The increase in the wage indexes of urban hospitals receiving the rural floor was offset by a nationwide decrease in all hospitals' wage indexes of approximately 0.67 percent. In Massachusetts, that meant that 36 urban hospitals received a wage index based on hospital wages in Nantucket, an island that is home to the only rural hospital contributing to the State's rural floor wage index. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38557), we estimated that those 36 hospitals would receive an additional $44 million in inpatient payments for the year. These increased payments were offset by decreased payments to hospitals nationwide, and those decreases were not based on actual local wage rates but on the current rural floor calculation.

As acknowledged by the OIG, CMS has long recognized the disparate impacts and unintended outcomes of the rural floor. We have stated that the rural floor creates a benefit for a minority of States that is then funded by a majority of States, including States that are overwhelmingly rural in character (73 FR 23528 and 23622). We also have stated that ''as a result of hospital actions not envisioned by Congress, the rural floor is resulting in significant disparities in wage index and, in some cases, resulting in situations where all hospitals in a State receive a wage index higher than that of the single highest wage index urban hospital in the State'' (76 FR 42170 and 42212).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41748), we indicated that wage index disparities associated with the rural floor significantly increased in FY 2019 with the urban to rural reclassification of an urban hospital in Massachusetts. We also note that Massachusetts is not the only State where urban hospitals reclassified as rural under § 412.103 have a significant impact on the State's rural floor. This also occurs, for example, in Arizona and Connecticut. The rural floor policy was meant to address anomalies of some urban hospitals being paid less than the average rural hospital in their States, not to raise the payments of many hospitals in a State to the high wage level of a geographically urban hospital.

We note that, for FY 2020, the urban Massachusetts hospital reclassified as rural under § 412.103 has an approved MGCRB reclassification back to its geographic location, and, therefore, its MGCRB reclassification is used for wage index calculation and payment purposes in this proposed rule (that is, this hospital would not be considered rural for wage index purposes). However, under our current wage index policy, the hospital would be able to influence the Massachusetts rural floor by withdrawing or terminating its MGCRB reclassification in accordance with the regulation at § 412.273 for FY 2020 or subsequent years.

Returning to our simplified example, for purposes of illustrating the impact of an urban to rural reclassification on the calculation of the rural floor under current policy, again assume that the rural wage index for a State is 1.1000. Therefore, under current policy, the rural floor for that State would be 1.1000. Any urban hospital with a wage index value below 1.1000 in that State would have its wage index value raised to 1.1000. However, now assume that one urban hospital in that State subsequently reclassifies from urban to rural and raises the rural wage index from 1.1000 to 1.2000. Now, solely because of a geographically urban hospital, the rural floor in that State would go from 1.1000 to 1.2000 under current policy.

As noted by OIG in the November 2018 report referenced above, the stated legislative intent of the rural floor was to correct the ''anomaly'' of ''some urban hospitals being paid less than the average rural hospital in their States.'' (Report 105–149 of the Committee on the Budget, House of Representatives, to Accompany H.R. 2015, June 24, 1997, section 10205, page 1305.) We believe that urban to rural reclassifications have stretched the rural floor provision beyond a policy designed to address such anomalies. Rather than raising the payment of some urban hospitals to the level of the average rural hospital in their State, urban hospitals may have their payments raised to the relatively high level of one or more geographically urban hospitals reclassified as rural. The current state of affairs with respect to urban to rural reclassifications goes beyond the general criticisms of the rural floor policy by MedPAC, CMS, OIG, and many stakeholders. We believe an adjustment is necessary to address the unanticipated effects of urban to rural reclassifications on the rural floor and the resulting wage index disparities, including the inappropriate wage index disparities caused by the manipulation of the rural floor policy by some hospitals.

Therefore, given the circumstances described above, the comments received on the request for information, and that urban to rural reclassifications have stretched the rural floor provision beyond a policy designed to address anomalies of some urban hospitals being paid less than the average rural hospital in their States, we are proposing to remove urban to rural reclassifications from the calculation of the rural floor. In other words, under our proposal, beginning in FY 2020, the rural floor would be calculated without including the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented at § 412.103). We believe our proposed calculation methodology is permissible under section 1886(d)(8)(E) of the Act and the rural floor statute (section 4410 of Pub. L. 105–33). Section 1886(d)(8)(E) of the Act does not specify where the wage data of reclassified hospitals must be included. Therefore, we believe we have discretion to exclude the wage data of such hospitals from the calculation of the rural floor. Furthermore, the rural floor statute does not specify how the rural floor wage index is to be calculated or what data are to be included in the calculation. Therefore, we also believe we have discretion under the rural floor statute to exclude the wage data of hospitals reclassified under section 1886(d)(8)(E) of the Act from the calculation of the rural floor. We believe this proposed policy is necessary and appropriate to address the unanticipated effects of rural reclassifications on the rural floor and the resulting wage index disparities, including the effects of the manipulation of the rural floor by certain hospitals. As discussed above, the inclusion of reclassified hospitals in the rural floor calculation has had the unforeseen effect of exacerbating the wage index disparities between low and high wage index hospitals. Therefore, under our proposal, in the case of Massachusetts, for example, the geographically rural hospital in Nantucket would still be included in the calculation of the rural floor for Massachusetts, but a geographically urban hospital reclassified under § 412.103 would not.

Returning to our simplified example for purposes of illustrating the impact of the proposed policy, again assume that the rural wage index for a State is 1.1000 without any hospital in the State having reclassified from urban to rural. Therefore, the rural floor for that State would be 1.1000. Any urban hospital

with a wage index value below 1.1000 in that State would have its wage index value raised to 1.1000. However, again assume that one urban hospital in that State subsequently reclassifies from urban to rural and raises the rural wage index from 1.1000 to 1.2000. Under our proposed policy, the rural floor in that State would not go from 1.1000 to 1.2000, but would remain at 1.1000 because urban to rural reclassifications would no longer impact the rural floor.

As we discuss earlier, the purpose of our proposal to calculate the rural floor without including the wage data of urban hospitals reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented at § 412.103) is to address wage index disparities that result when urban hospitals may have their payments raised to the relatively high level of one or more geographically urban hospitals reclassified as rural. In particular, we believe that no urban hospital not reclassified as rural should have its payments raised to the relatively high level of one or more geographically urban hospitals reclassified as rural, and we believe it would be inappropriate to prevent this for one class of urban hospitals not reclassified as rural (that is, under the rural floor provision) but allow this for another. As such, for consistent treatment of urban hospitals not reclassified as rural, we also are proposing to apply the provisions of section 1886(d)(8)(C)(iii) of the Act without including the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented at § 412.103). Because section 1886(d)(8)(C)(iii) of the Act provides that reclassifications under section 1886(d)(8)(B) of the Act and section 1886(d)(10) of the Act may not reduce any county's wage index below the wage index for rural areas in the State, we are making this proposal to help ensure no urban hospitals not reclassified as rural, including those hospitals with no reclassification as well as those hospitals reclassified under section 1886(d)(8)(B) of the Act or section 1886(d)(10) of the Act, have their payments raised to the relatively high level of one or more geographically urban hospitals reclassified as rural. Specifically, for purposes of applying the provisions of section 1886(d)(8)(C)(iii) of the Act, we are proposing to remove urban to rural reclassifications from the calculation of ''the wage index for rural areas in the State in which the county is located'' referred to in section 1886(d)(8)(C)(iii) of the Act.

d. Proposed Transition for Hospitals Negatively Impacted

We recognize that, absent further adjustments, the combined effect of the proposed changes to the FY 2020 wage index could lead to significant decreases in the wage index values for some hospitals depending on the data for the final rule. In the past, we have proposed and finalized budget neutral transition policies to help mitigate any significant negative impacts on hospitals of certain wage index proposals, and we believe it would be appropriate to propose a transition policy here for the same purpose. For example, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49963), we finalized a budget neutral transition to address certain wage index changes that occurred under the new OMB CBSA delineations.

Therefore, for FY 2020, we are proposing a transition wage index to help mitigate any significant decreases in the wage index values of hospitals compared to their final wage indexes for FY 2019. Specifically, for FY 2020, we are proposing to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019. In other words, we are proposing that a hospital's final wage index for FY 2020 would not be less than 95 percent of its final wage index for FY 2019. This proposed transition would allow the effects of our proposed policies to be phased in over 2 years with no estimated reduction in the wage index of more than 5 percent in FY 2020 (that is, no cap would be applied the second year). We believe 5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in the wage index for FY 2020. However, we are seeking public comments on alternative levels for the cap and accompanying rationale. Under the proposed transition policy, we would compute the proposed FY 2020 wage index for each hospital as follows.

Step 1.—Compute the proposed FY 2020 ''uncapped'' wage index that would result from the implementation of proposed changes to the FY 2020 wage index.

Step 2.—Compute a proposed FY 2020 ''capped'' wage index which would equal 95 percent of that provider's FY 2019 final wage index.

Step 3.—The proposed FY 2020 wage index is the greater of the ''uncapped'' wage index computed in Step 1 or the ''capped'' wage index computed in Step 2.

e. Transition Budget Neutrality

We are proposing to apply a budget neutrality adjustment to the standardized amount so that our proposed transition (described in section III.N.3.c. of the preamble of this proposed rule) for hospitals that could be negatively impacted is implemented in a budget neutral manner under our authority in section 1886(d)(5)(I) of the Act. We note that implementing the proposed transition wage index in a budget neutral manner is consistent with past practice (for example, 79 FR 50372) where CMS has used its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to budget neutralize transition wage index policies when such policies allow for the application of a transitional wage index only when it benefits the hospital. We believed, and continue to believe, that it would be appropriate to ensure that such policies do not increase estimated aggregate Medicare payments beyond the payments that would be made had we never proposed these transition policies (79 FR 50732). Therefore, for FY 2020, we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to apply a budget neutrality adjustment to the standardized amount so that our proposed transition (described in section III.N.3.d. of the preamble of this proposed rule) for hospitals negatively impacted is implemented in a budget neutral manner.

Specifically, we are proposing to apply a budget neutrality adjustment to ensure that estimated aggregate payments under our proposed transition (described in section III.N.3.d. of the preamble of this proposed rule) for hospitals negatively impacted by our proposed wage index policies would equal what estimated aggregate payments would have been without the proposed transition for hospitals negatively impacted. To determine the associated budget neutrality factor, we compared estimated aggregate IPPS payments with and without the proposed transition. To achieve budget neutrality for the proposed transition policy, we are proposing to apply a budget neutrality adjustment factor of 0.998349 to the FY 2020 standardized amount, as further discussed in section I.A.4.f. of the Addendum to this proposed rule. If this policy is adopted in the final rule, this number would be updated based on the final rule data.

We note that our proposal, discussed in section III.N.3.c. of the preamble of this proposed rule, to prevent inappropriate payment increases due rural reclassifications under § 412.103 would also be budget neutral, but this budget neutrality would occur through the proposed budget neutrality

adjustments for geographic reclassifications and the rural floor that are discussed in the Addendum to this proposed rule.

IV. Other Decisions and Proposed Changes to the IPPS for Operating System

A. Proposed Changes to MS–DRGs Subject to Postacute Care Transfer Policy and MS–DRG Special Payments Policies (§ 412.4)

1. Background

Existing regulations at 42 CFR 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy set forth in § 412.4(f) provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full MS–DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases also are eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to the fixed-loss outlier threshold for nontransfer cases (adjusted for geographic variations in costs), divided by the geometric mean length of stay for the MS–DRG, and multiplied by the length of stay for the case, plus 1 day.

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. The statute directs us to identify MS–DRGs based on a high volume of discharges to postacute care facilities and a disproportionate use of postacute care services. As discussed in the FY 2006 IPPS final rule (70 FR 47416), we determined that the 55th percentile is an appropriate level at which to establish these thresholds. In that same final rule (70 FR 47419), we stated that we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific MS–DRG.

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes a special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6)). For an MS–DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG severity level group will qualify under the MS–DRG special payment methodology policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

Prior to the enactment of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), under section 1886(d)(5)(J) of the Act, a discharge was deemed a ''qualified discharge'' if the individual was discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection (d) hospital.
- A skilled nursing facility.
- Related home health services provided by a home health agency provided within a timeframe established by the Secretary (beginning within 3 days after the date of discharge).

Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J)(ii) of the Act to also include discharges to hospice care provided by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. Accordingly, effective for discharges occurring on or after October 1, 2018, if a discharge is assigned to one of the MS–DRGs subject to the postacute care transfer policy and the individual is transferred to hospice care by a hospice program, the discharge is subject to payment as a transfer case. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41394), we made conforming amendments to § 412.4(c) of the regulation to include discharges to hospice care occurring on or after October 1, 2018 as qualified discharges. We specified that hospital bills with a Patient Discharge Status code of 50 (Discharged/Transferred to Hospice—Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) are subject to the postacute care transfer policy in accordance with this statutory amendment. Consistent with our policy for other qualified discharges, CMS claims processing software has been revised to identify cases in which hospice benefits were billed on the date of hospital discharge without the appropriate discharge status code. Such claims will be returned as unpayable to the hospital and may be rebilled with a corrected discharge code.

2. Proposed Changes for FY 2020

As discussed in section II.F. of the preamble of this FY 2020 IPPS/LTCH PPS proposed rule, based on our analysis of FY 2018 MedPAR claims data, we are proposing to make changes to a number of MS–DRGs, effective for FY 2020. Specifically, we are proposing to:

- Reassign procedure codes from MS–DRGs 216 through 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, CC and without CC/MCC, respectively), MS–DRGs 219 through 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, CC and without CC/MCC, respectively), and MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectively) and create new MS–DRGs 319 and 320 (Other Endovascular Cardiac Valve Procedures with and without MCC, respectively); and
- Delete MS–DRGs 691 and 692 (Urinary Stones with ESW Lithotripsy with CC/MCC and without CC/MCC,

respectively) and revise the titles for MS–DRGs 693 and 694 to ''Urinary Stones with MCC'' and ''Urinary Stones without MCC'', respectively.

In light of the proposed changes to these MS–DRGs for FY 2020, according to the regulations under § 412.4(d), we evaluated these MS–DRGs using the general postacute care transfer policy criteria and data from the FY 2018 MedPAR file. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). We continue to believe it is appropriate to reassess MS–DRGs when proposing reassignment of procedure codes or diagnosis codes that would result in material changes to an MS–DRG. MS–DRGs 216, 217, 218, 219, 220, and 221 are currently subject to the postacute care transfer policy. As a result of our review, these MS–DRGs, as proposed to be revised, would continue to qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. MS–DRGs 273 and 274 are also currently subject to the postacute care transfer policy and MS–DRGs 693 and 694 are currently not subject to the postacute care transfer policy. As a result of our review, these MS–DRGs, as proposed to be revised, would not qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. Proposed new MS–DRGs 319 and 320 also would not qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. Therefore, we are proposing to remove MS–DRGs 273 and 274 from the list of MS–DRGs that are subject to the postacute care transfer policy. We note that MS–DRGs that are subject to the postacute care transfer policy for FY 2019 and are not revised will continue to be subject to the policy in FY 2020.

Using the December 2018 update of the FY 2018 MedPAR file, we developed the chart below, which sets forth the most recent analysis of the postacute care transfer policy criteria completed for this proposed rule with respect to each of these proposed new or revised MS–DRGs. For the FY 2020 final rule, we intend to update this analysis using the most recent available data at that time.

Proposed new or revised MS–DRGS	MS–DRG title	Total cases	Postacute care transfers (55th percentile: 1,400)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 8.5132%)	Current postacute care transfer policy status	Proposed postacute care transfer policy status
216	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC.	5,733	4,196	1,643	28.6586	Yes	Yes.
217	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC.	2,317	1,551	424	18.2995	Yes	Yes.
218	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC.	599	*328	67	11.1853	Yes	**Yes.
219	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC.	13,177	9,216	3,450	26.182	Yes	Yes.
220	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC.	16,201	10,247	2,914	17.9865	Yes	Yes.
221	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC.	6,070	3,205	239	*3.9374	Yes	**Yes.
273	Percutaneous Intracardiac Procedures with MCC.	5,958	2,152	280	*4.6996	Yes	No.
274	Percutaneous Intracardiac Procedures without MCC.	0	*0	0	*0	Yes	No.
319	Other Endovascular Cardiac Valve Procedures with MCC.	1,651	*842	191	11.5687	New	No.
320	Other Endovascular Cardiac Valve Procedures without MCC.	707	*229	30	*4.2433	New	No.
693	Urinary Stones with MCC	1,300	*541	81	*6.2308	No	No.
694	Urinary Stones without MCC	8,025	1,739	185	*2.3053	No	No.

* Indicates a current postacute care transfer policy criterion that the MS–DRG did not meet.

** As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS–DRGs that share the same base MS–DRG will all qualify under the postacute care transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

During our annual review of proposed new or revised MS–DRGs and analysis of the December 2018 update of the FY 2018 MedPAR file, we reviewed the list of proposed revised or new MS–DRGs that qualify to be included on the list of MS–DRGs subject to the postacute care transfer policy for FY 2020 to determine if any of these MS–DRGs would also be subject to the special payment methodology policy for FY 2020. Based on our analysis of proposed changes to MS–DRGs included in this proposed rule, we determined that proposed revised MS–DRGs 216, 217, 218, 219, 220, and 221 would continue to meet the criteria for the MS–DRG special payment methodology. Because we are proposing to remove MS–DRGs 273 and 274 from the list of MS–DRGs subject to the postacute care transfer policy, we also are proposing to remove these MS–DRGs from the list of MS–DRGs subject to the MS–DRG special payment methodology, effective FY 2020.

For the FY 2020 final rule, we intend to update this analysis using the most recent available data at that time.

Proposed revised MS–DRG	MS–DRG title	Geometric mean length of stay	Average charges of 1-day discharges	50 Percent of average charges for all cases within MS–DRG	Current special payment policy status	Proposed special payment policy status
216	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC.	14.1126	0	$186,087.76	Yes	Yes.
217	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC.	8.9229	147,964.00	128,141.91	Yes	Yes.
218	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC.	6.46878	203,555.50	101,286.68	Yes	Yes.
219	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC.	9.48987	185,157.20	152,482.54	Yes	Yes.
220	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC.	6.3373	115,955.36	101,812.54	Yes	Yes.
221	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC.	4.66413	127,074.88	82,400.23	Yes	Yes.

The proposed postacute care transfer and special payment policy status of these MS–DRGs is reflected in Table 5 associated with this proposed rule, which is listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website.

B. Proposed Changes in the Inpatient Hospital Update for FY 2020 (§ 412.64(d))

1. Proposed FY 2020 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2020, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2019. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2020 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to—

(a) A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act;

(b) A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act; and

(c) An adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment).

Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the MFP adjustment may result in the applicable percentage increase being less than zero.

In compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we replaced the FY 2010-based IPPS operating market basket with the rebased and revised 2014-based IPPS operating market basket, effective with FY 2018.

We are proposing to base the proposed FY 2020 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2018 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2018, which is estimated to be 3.2 percent. We also are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket and the MFP adjustment), we would use such data, if appropriate, to determine the FY 2020 market basket update and the MFP adjustment in the final rule.

For FY 2020, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount, as specified in the table that appears later in this section.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS website at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic

forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509), beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using the revised series developed by IGI to proxy the aggregate capital inputs. Specifically, in order to generate a forecast of MFP, IGI forecasts BLS aggregate capital inputs using a regression model. A complete description of the MFP projection methodology is available on the CMS website at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* As discussed in the FY 2016 IPPS/LTCH PPS final rule, if IGI makes changes to the MFP methodology, we will announce them on our website rather than in the annual rulemaking.

For FY 2020, we are proposing an MFP adjustment of 0.5 percentage point. Similar to the market basket update, for this proposed rule, we used IGI's fourth quarter 2018 forecast of the MFP adjustment to compute the proposed FY 2020 MFP adjustment. As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2020 market basket update and the MFP adjustment for the final rule.

Based on these data, for this proposed rule, we have determined four proposed applicable percentage increases to the standardized amount for FY 2020, as specified in the following table:

PROPOSED FY 2020 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2020	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase	3.2	3.2	3.2	3.2
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	−0.8	−0.8
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	−2.4	0	−2.4
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.5	−0.5	−0.5	−0.5
Proposed Applicable Percentage Increase Applied to Standardized Amount	2.7	0.3	1.9	−0.5

We are proposing to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to add paragraph (viii) to § 412.64(d)(1) to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less an MFP adjustment. (As noted above, section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. (Under current law, the MDH program is effective for discharges on or before September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430).)

For FY 2020, we are proposing the following updates to the hospital-specific rates applicable to SCHs and MDHs: A proposed update of 2.7 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 1.9 percent for a hospital that fails to submit quality data and is a meaningful EHR user; a proposed update of 0.3 percent for a hospital that submits quality data and is not a meaningful EHR user; and a proposed update of −0.5 percent for a hospital that fails to submit quality data and is not a meaningful EHR user. As noted previously, for this FY 2020 IPPS/LTCH PPS proposed rule, we are using IGI's fourth quarter 2018 forecast of the 2014-based IPPS market basket update with historical data through third quarter 2018. Similarly, we are using IGI's fourth quarter 2018 forecast of the MFP adjustment. We are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such data, if appropriate, to determine the update in the final rule.

2. Proposed FY 2020 Puerto Rico Hospital Update

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56937 through 56938), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to determine an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this proposed rule. Accordingly, in this FY 2020 IPPS/LTCH PPS proposed rule, for FY 2020, we are proposing an applicable percentage increase of 2.7 percent to the

standardized amount for hospitals located in Puerto Rico.

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2020.

C. Rural Referral Centers (RRCs) Proposed Annual Updates to Case-Mix Index and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive some special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in Subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (c)(5) and the September 30, 1988 **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The proposed national median CMI value for FY 2020 is based on the CMI values of all urban hospitals nationwide, and the proposed regional median CMI values for FY 2020 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These proposed values are based on discharges occurring during FY 2018 (October 1, 2017 through September 30, 2018), and include bills posted to CMS' records through December 2018.

In this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2019, they must have a CMI value for FY 2018 that is at least—

- 1.68555 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region are set forth in the table below. We intend to update the proposed CMI values in the FY 2020 final rule to reflect the updated FY 2018 MedPAR file, which will contain data from additional bills received through March 2019.

Region	Proposed case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.4231
2. Middle Atlantic (PA, NJ, NY)	1.492
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.576
4. East North Central (IL, IN, MI, OH, WI)	1.5921
5. East South Central (AL, KY, MS, TN)	1.5579
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.67025
7. West South Central (AR, LA, OK, TX)	1.7172
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7769
9. Pacific (AK, CA, HI, OR, WA)	1.6699

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective

payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. For FY 2020, we are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2017 (that is, October 1, 2016 through September 30, 2017), which are the latest cost report data available at the time this proposed rule was developed. Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2019, must have, as the number of discharges for its cost reporting period that began during FY 2017, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. The proposed numbers of discharges are set forth in the table below. We intend to update these numbers in the FY 2020 final rule based on the latest available cost report data.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,542
2. Middle Atlantic (PA, NJ, NY)	10,154
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,653
4. East North Central (IL, IN, MI, OH, WI)	8,379
5. East South Central (AL, KY, MS, TN)	7,627
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,850
7. West South Central (AR, LA, OK, TX)	5,468
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,618
9. Pacific (AK, CA, HI, OR, WA)	8,618

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this proposed rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

D. Proposed Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act. Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399), section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. (Section 50204 also extended prior changes to the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals through FY 2018.) Beginning with FY 2023, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011. (For additional information on the low-volume hospital payment adjustment prior to FY 2018, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56941 through 56943). For additional information on the low-volume hospital payment adjustment for FY 2018, we refer readers to the FY 2018 IPPS notice (CMS–1677–N) that appeared in the **Federal Register** on April 26, 2018 (83 FR 18301 through 18308).)

2. Temporary Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology for FYs 2019 Through 2022

As discussed earlier, section 50204 of the Bipartisan Budget Act of 2018 further modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. Specifically, the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act were amended to specify that, for FYs 2019 through 2022, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Section 1886(d)(12)(D) of the Act was also amended to provide that, for discharges occurring in FYs 2019 through 2022, the Secretary shall determine the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399), to implement this requirement, we specified a continuous, linear sliding scale formula to determine the low volume hospital payment adjustment for FYs 2019 through 2022 that is similar to the continuous, linear sliding scale formula used to determine the low-volume hospital payment adjustment originally established by the Affordable Care Act and implemented in the regulations at § 412.101(c)(2)(ii) in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240 through 50241). Consistent with the statute, we provided that qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. As such, for qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, the low-volume hospital payment adjustment for FYs 2019 through 2022 is calculated using the following formula:

$$\text{Low-Volume Hospital Payment Adjustment} = 0.25 - [0.25/3300] \times (\text{number of total discharges} - 500) = (95/330) - (\text{number of total discharges}/13{,}200).$$

For this purpose, we specified that the ''number of total discharges'' is determined as total discharges, which includes Medicare and non-Medicare discharges during the fiscal year, based on the hospital's most recently submitted cost report. The low-volume hospital payment adjustment for FYs 2019 through 2022 is set forth in the regulations at 42 CFR 412.101(c)(3).

3. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking (for example, the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)

As explained earlier, for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and § 412.101(b)(2)(iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital should refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) in order to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

As also discussed in the FY 2019 IPPS/LTCH PPS final rule, in addition to the discharge criterion, for FY 2019 and for subsequent fiscal years, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in § 412.101(b)(2)(i) or § 412.101(b)(2)(iii) for the fiscal year. Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2020, as was the case for FY 2019, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital. (We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

In accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low-volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with this previously established process, for FY 2020, we are proposing that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Consistent with historical practice, for FY 2020, we are proposing that a hospital's written request must be received by its MAC no later than September 1, 2019 in order for the low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2019. If a hospital's written request for low-volume hospital status for FY 2020 is received after September 1, 2019, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2020 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination. We note that this proposal is consistent with the process for requesting and obtaining the low-volume hospital payment adjustment for FY 2019 (83 FR 41399 through 41400).

Under this process, a hospital receiving the low-volume hospital payment adjustment for FY 2019 may continue to receive a low-volume hospital payment adjustment for FY 2020 without reapplying if it continues to meet the applicable mileage and discharge criteria (which, as discussed previously, are the same qualifying criteria that apply for FY 2019). In this case, a hospital's request can include a verification statement that it continues to meet the mileage criterion applicable for FY 2020. (Determination of meeting the discharge criterion is discussed earlier in this section.) We note that a hospital must continue to meet the applicable qualifying criteria as a low-volume hospital (that is, the hospital must meet the applicable discharge criterion and mileage criterion for the fiscal year) in order to receive the payment adjustment in that fiscal year; that is, low-volume hospital status is not based on a ''one-time'' qualification (75 FR 50238 through 50275). Consistent with historical policy, a hospital must submit its request, including this written verification, for each fiscal year for which it seeks to receive the low-volume hospital payment adjustment, and in accordance with the timeline described earlier.

4. Proposed Conforming Changes To Codify Certain Changes to the Low-Volume Hospital Payment Adjustment for FYs 2011 Through 2017 Provided by Section 429 of the Consolidated Appropriations Act, 2018

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38188 through 38189), for the reasons discussed in that rule, we adopted a parallel adjustment in the regulations at § 412.101(e) which specifies that, for discharges occurring in FY 2018 and subsequent years, only the distance between Indian Health Service (IHS) and Tribal hospitals (collectively referred to here as ''IHS hospitals'') will be considered when assessing whether an IHS hospital meets the mileage criterion under § 412.101(b)(2), and similarly, only the distance between non-IHS hospitals would be considered when assessing whether a non-IHS hospital meets the mileage criterion under § 412.101(b)(2). Section 429 of the Consolidated Appropriations Act, 2018, which was enacted on March 23, 2018, subsequently amended section 1886(d)(12)(C) of the Act by adding a new clause (iii) specifying that, for purposes of determining whether an IHS or a non-IHS hospital meets the mileage criterion under section 1886(d)(12)(C)(i) of the Act with respect to FY 2011 or a succeeding year, the Secretary shall apply the policy described in the regulations at § 412.101(e) (as in effect on the date of enactment). In other words, under this statutory change, the special treatment with respect to the proximities between IHS and non-IHS hospitals as set forth in § 412.101(e) for discharges occurring in FY 2018 and subsequent fiscal years is also applicable for purposes of applying the mileage criterion for the low-volume hospital payment adjustment for FYs 2011 through 2017. We refer readers to the notice that appeared in the **Federal Register** on August 23, 2018 (83 FR 42596 through 42600) for further detail on the process for requesting the low-volume hospital payment adjustment for any applicable fiscal years between FY 2011 and FY 2017 under the provisions of section 429 of the Consolidated Appropriations Act, 2018, including the details on the limitations under the reopening rules at 42 CFR 405.1885.

In this proposed rule, we are proposing to make conforming changes to the regulatory text at § 412.101(e) to reflect the changes to the low-volume hospital payment adjustment policy in accordance with the amendments made by section 429 of the Consolidated Appropriations Act, 2018. Specifically, we are proposing to revise § 412.101(e) to specify that, subject to the reopening rules at 42 CFR 405.1885, a qualifying hospital may request the application of the policy set forth in proposed amended § 412.101(e)(1) for FYs 2011 through 2017. As noted previously, the process for requesting the low-volume hospital payment adjustment for any applicable fiscal years between FY 2011 and 2017 under the provisions of section 429 of the Consolidated Appropriations Act, 2018, as well as further discussion on the limitations under the reopening rules at 42 CFR 405.1885, are described in the August 23, 2018 **Federal Register** notice (83 FR 42596 through 425600). We note that proposed amended § 412.101(e) would apply to discharges occurring in FY 2011 through FY 2017, consistent with the provisions of section 429 of the Consolidated Appropriations Act, 2018. To the extent that these proposed revisions could be viewed as retroactive rulemaking, they would be authorized under section 1871(e)(1)(A)(i) of the Act as the Secretary has determined that these changes are necessary to comply with the statute as amended by the Consolidated Appropriations Act, 2018.

E. Indirect Medical Education (IME) Payment Adjustment Factor (§ 412.105)

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2020, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2020 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

F. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2020 (§ 412.106)

1. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: The ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for

the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this final rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

As provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress. We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

2. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As explained earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014

IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemaking for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. In this proposed rule, we are discussing our specific policies for FY 2020 with respect to the following hospitals:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).
- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41402 through 41403), CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland Total Cost of Care (TCOC) Model, which began on January 1, 2019. Under the Maryland TCOC Model, Maryland hospitals will not be paid under the IPPS in FY 2020, and will be ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.
- Sole community hospitals (*SCHs) that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).
- *Medicare-dependent, small rural hospitals (MDHs)* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for discharges on or after October 1, 2017, through September 30, 2022. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for empirically justified Medicare DSH and uncompensated care payments as we do for all other IPPS hospitals. Due to the extension of the MDH program, MDHs will continue to be paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years. Accordingly, we will continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). Our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year. In addition, as we do for all IPPS hospitals, we will calculate a numerator for Factor 3 for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator for Factor 3 will be based on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.
- *IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced Initiative (BPCI Advanced) model starting October 1, 2018,* will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. For further information regarding the BPCI Advanced model, we refer readers to the CMS website at: *https://innovation.cms.gov/initiatives/bpci-advanced/.*
- *IPPS hospitals that are participating in the Comprehensive Care for Joint Replacement Model* (80 FR 73300) continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments.
- *Hospitals participating in the Rural Community Hospital Demonstration Program* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 114–255). The period of performance for this 5-year extension period ended December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. At the time of issuance of this proposed rule, there are 29 hospitals participating in the demonstration program. Under the payment methodology that applies during the second 5 years of the extension period under the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are also excluded from receiving interim and final uncompensated care payments.

3. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising MACs to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html.*

4. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. Below we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2019, and our proposed policies for FY 2020.

a. Proposed Calculation of Factor 1 for FY 2020

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between: (1) The aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

As we did for FY 2019, in this FY 2020 IPPS/LTCH PPS proposed rule, in order to determine Factor 1 in the uncompensated care payment formula for FY 2020, we are proposing to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. These estimates will not be revised or updated after we know the final Medicare DSH payments for FY 2020. Therefore, in order to determine the two elements of proposed Factor 1 for FY 2020 (Medicare DSH payments prior to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments after application of section 1886(r)(1) of the Act), for this proposed rule, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File. The determination of the amount of DSH payments is partially based on the Office of the Actuary's Part A benefits projection model. One of the results of this model is inpatient hospital spending. Projections of DSH payments require projections for expected increases in utilization and case-mix. The assumptions that were used in making these projections and the resulting estimates of DSH payments for FY 2017 through FY 2020 are discussed in the table titled ''Factors Applied for FY 2017 through FY 2020 to Estimate Medicare DSH Expenditures Using FY 2016 Baseline.''

For purposes of calculating Factor 1 and modeling the impact of this FY 2020 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's December 2018 Medicare DSH estimates, which were based on data from the September 2018 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2019 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2019 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the December 2018 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments

that would be made without regard to section 1886(r) of the Act), Maryland hospitals, which are not eligible to receive DSH payments, were also excluded from the Office of the Actuary's December 2018 Medicare DSH estimates. The 29 hospitals that are participating in the Rural Community Hospital Demonstration Program were also excluded from these estimates because, under the payment methodology that applies during the second 5 years of the extension period, these hospitals are not eligible to receive empirically justified Medicare DSH payments or interim and final uncompensated care payments.

For this proposed rule, using the data sources discussed above, the Office of the Actuary's December 2018 estimate for Medicare DSH payments for FY 2020, without regard to the application of section 1886(r)(1) of the Act, is approximately $16.857 billion. Therefore, also based on the December 2018 estimate, the estimate of empirically justified Medicare DSH payments for FY 2020, with the application of section 1886(r)(1) of the Act, is approximately $4.214 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2020). Under § 412.l06(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in this proposed rule, we are proposing that Factor 1 for FY 2020 would be $12,643,011,209.74, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2020 ($16,857,348,279.65 minus $4,214,337,069.91).

The Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President's Budget. As we have in the past, for additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at: *https://www.whitehouse.gov/omb/budget.* We recognize that our reliance on the economic assumptions and actuarial analysis used to develop the President's Budget in estimating Factor 1 has an impact on stakeholders who wish to replicate the Factor 1 calculation, such as modelling the relevant Medicare Part A portion of the budget, but we believe commenters are able to meaningfully comment on our proposed estimate of Factor 1 without replicating the President's Budget.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html?redirect=/reportstrustfunds/* under ''Downloads.'' We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

We also refer readers to the Actuarial Report on the Financial Outlook for Medicaid for a discussion of general issues regarding Medicaid projections.

In this proposed rule, we include information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's estimate of Factor 1. In summary, we indicate the historical HCRIS data update OACT used to identify Medicare DSH payments, we explain that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provide the components of all the update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also includes a description of the ''Other'' and ''Discharges'' assumptions, and also provides additional information regarding how we address the Medicaid and CHIP expansion.

The Office of the Actuary's estimates for FY 2020 for this proposed rule began with a baseline of $13.981 billion in Medicare DSH expenditures for FY 2016. The following table shows the factors applied to update this baseline through the current estimate for FY 2020:

FACTORS APPLIED FOR FY 2017 THROUGH FY 2020 TO ESTIMATE MEDICARE DSH EXPENDITURES USING FY 2016 BASELINE

FY	Update	Discharges	Case-mix	Other	Total	Estimated DSH payment (in billions) *
2017	1.0015	0.9986	1.004	1.0751	1.0795	15.093
2018	1.018088	0.9819	1.018	1.0345	1.0528	15.889
2019	1.0185	0.9791	1.005	1.02206	1.0243	16.275
2020	1.032	1.0055	1.005	0.9932	1.0358	16.857

* Rounded.

In this table, the discharges column shows the increase in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FY 2017 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2018 is based on preliminary data for 2018. The discharge figures for FY 2019 and FY 2020 are assumptions based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The case-mix column shows the increase in case-mix for IPPS hospitals. The case-mix figures for FY 2017 and FY 2018 are based on actual data adjusted by a completion factor. The FY 2019 and FY 2020 increases are estimates based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient

hospital discharges and the IPPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy). In addition, the ''Other'' column includes a factor for the Medicaid expansion due to the Affordable Care Act. The factor for Medicaid expansion was developed using public information and statements for each State regarding its intent to implement the expansion. Based on this information, it is assumed that 50 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2016 resided in States that had elected to expand Medicaid eligibility and, for 2017 and thereafter, that 55 percent of such individuals would reside in expansion States. In the future, these assumptions may change based on actual participation by States. For a discussion of general issues regarding Medicaid projections, we refer readers to the 2017 Actuarial Report on the Financial Outlook for Medicaid, which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2017.pdf.* We note that, in developing their estimates of the effect of Medicaid expansion on Medicare DSH expenditures, our actuaries have assumed that the new Medicaid enrollees are healthier than the average Medicaid recipient and, therefore, use fewer hospital services. Specifically, based on data from the President's Budget, the OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 50 percent of the average per capita expenditures for a pre-expansion Medicaid beneficiary due to the better health of these beneficiaries. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion.

The table below shows the factors that are included in the ''Update'' column of the above table:

FY	Market basket percentage	Affordable Care Act payment reductions	Multifactor productivity adjustment	Documentation and coding	Total update percentage
2017	2.7	−0.75	−0.3	−1.5	0.15
2018	2.7	−0.75	−0.6	0.4588	1.8088
2019	2.9	−0.75	−0.8	0.5	1.885
2020	3.2	0	−0.5	0.5	3.2

Note: All numbers are based on the FY 2020 President's Budget projections, except for the FY 2020 percentages, which are based on the most recent forecast. We refer readers to section IV.B. of the preamble of this proposed rule for a complete discussion of the proposed changes in the inpatient hospital update for FY 2020.

b. Calculation of Proposed Factor 2 for FY 2020

(1) Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act provides that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019. In FY 2020 and subsequent fiscal years, there is no longer a reduction. We note that, unlike section 1886(r)(2)(B)(i) of the Act, which governed the calculation of Factor 2 for FYs 2014, 2015, 2016, and 2017, section 1886(r)(2)(B)(ii) of the Act permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. In addition, for FY 2018 and subsequent years, the statute does not require that the estimate of the percent of individuals who are uninsured be limited to individuals who are under 65 years of age.

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197), in our analysis of a potential data source for the rate of uninsurance for purposes of computing Factor 2 in FY 2018, we considered the following: (a) The extent to which the source accounted for the full U.S. population; (b) the extent to which the source comprehensively accounted for both public and private health insurance coverage in deriving its estimates of the number of uninsured; (c) the extent to which the source utilized data from the Census Bureau; (d) the timeliness of the estimates; (e) the continuity of the estimates over time; (f) the accuracy of the estimates; and (g) the availability of projections (including the availability of projections using an established estimation methodology that would allow for calculation of the rate of uninsurance for the applicable Federal fiscal year). As we explained in the FY 2018 IPPS/LTCH PPS final rule, these considerations are consistent with the statutory requirement that this estimate be based on data from the Census Bureau or other sources the Secretary determines appropriate and help to ensure the data source will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. We are proposing to use the same methodology as was used in FY 2018 and FY 2019 to determine Factor 2 for FY 2020.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198), we explained that we determined the source that, on balance, best meets all of these considerations is the uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA). The NHEA represents the government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA has been used to study numerous topics related to the health care sector, including, but not limited to, changes in the amount and cost of health services purchased and the payers or programs that provide or purchase these services; the economic causal factors at work in the health sector; the impact of policy changes, including major health reform; and comparisons to other countries' health spending. Of relevance to the determination of Factor 2 is that the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured because this mix is

integral to the well-established NHEA methodology. Below we describe some aspects of the methodology used to develop the NHEA that were particularly relevant in estimating the percent change in the rate of uninsurance for FY 2018 and FY 2019 that we believe continue to be relevant in developing the estimate for FY 2020. A full description of the methodology used to develop the NHEA is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/DSM-15.pdf.*

The NHEA estimates of U.S. population reflect the Census Bureau's definition of the resident-based population, which includes all people who usually reside in the 50 States or the District of Columbia, but excludes residents living in Puerto Rico and areas under U.S. sovereignty, members of the U.S. Armed Forces overseas, and U.S. citizens whose usual place of residence is outside of the United States, plus a small (typically less than 0.2 percent of population) adjustment to reflect Census undercounts. In past years, the estimates for Factor 2 were made using the CBO's uninsured population estimates for the under 65 population. For FY 2018 and subsequent years, the statute does not restrict the estimate to the measurement of the percent of individuals under the age of 65 who are uninsured. Accordingly, as we explained in the FY 2018 IPPS/LTCH PPS proposed and final rules, we believe it is appropriate to use an estimate that reflects the rate of uninsurance in the United States across all age groups. In addition, we continue to believe that a resident-based population estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than an estimate that reflects only legal residents. The NHEA estimates of uninsurance are for the total U.S. population (all ages) and not by specific age cohort, such as the population under the age of 65.

The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. Estimates of total PHI enrollment are available for 1960 through 2017, estimates of Medicaid, Medicare, and CHIP enrollment are available for the length of the respective programs, and all other estimates (including the more detailed estimates of direct-purchased and employer-sponsored insurance) are available for 1987 through 2017. The NHEA data are publicly available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html.*

In order to compute Factor 2, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. In developing the estimates for the NHEA, OACT's methodology included using the number of uninsured individuals for 1987 through 2009 based on the enhanced Current Population Survey (CPS) from the State Health Access Data Assistance Center (SHADAC). The CPS, sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States. (We refer readers to the website at: *http://www.census.gov/programs-surveys/cps.html.*) The enhanced CPS, available from SHADAC (available at: *http://datacenter.shadac.org*) accounts for changes in the CPS methodology over time. OACT further adjusts the enhanced CPS for an estimated undercount of Medicaid enrollees (a population that is often not fully captured in surveys that include Medicaid enrollees due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance).

To estimate the number of uninsured individuals for 2010 through 2014, the OACT extrapolates from the 2009 CPS data using data from the National Health Interview Survey (NHIS). The NHIS is one of the major data collection programs of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). The U.S. Census Bureau is the data collection agent for the NHIS. The NHIS results have been instrumental over the years in providing data to track health status, health care access, and progress toward achieving national health objectives. For further information regarding the NHIS, we refer readers to the CDC website at: *https://www.cdc.gov/nchs/nhis/index.htm.*

The next metrics needed to compute Factor 2 are projections of the rate of uninsurance in both calendar years 2019 and 2020. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. Those projections (currently for years 2018 through 2027) use the latest NHEA historical data, which presently run through 2017. The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. The sources for projected growth rates in enrollment for Medicare, Medicaid, and CHIP include the latest Medicare Trustees Report, the Medicaid Actuarial Report, or other updated estimates as produced by OACT. Projected rates of growth in enrollment for private health insurance and the uninsured are based largely on OACT's econometric models, which rely on the set of macroeconomic assumptions underlying the latest Medicare Trustees Report. Greater detail can be found in OACT's report titled ''Projections of National Health Expenditure: Methodology and Model Specification,'' which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf.*

The use of data from the NHEA to estimate the rate of uninsurance is consistent with the statute and meets the criteria we have identified for determining the appropriate data source. Section 1886(r)(2)(B)(ii) of the Act instructs the Secretary to estimate the rate of uninsurance for purposes of Factor 2 based on data from the Census Bureau or other sources the Secretary determines appropriate. The NHEA utilizes data from the Census Bureau; the estimates are available in time for the IPPS rulemaking cycle; the estimates are produced by OACT on an annual basis and are expected to continue to be produced for the foreseeable future; and projections are available for calendar year time periods that span the upcoming fiscal year. Timeliness and continuity are important considerations because of our need to be able to update this estimate annually. Accuracy is also a very important consideration and, all things being equal, we would choose the most accurate data source that sufficiently meets our other criteria.

(2) Proposed Factor 2 for FY 2020

Using these data sources and the methodologies described above, the OACT estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2019 and 2020 is 9.4 percent and 9.3 percent, respectively.[394] As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS has certified these estimates.

[394] Certification of Rates of Uninsured. March 28, 2019. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInPatientPPS/dsh.html.*

As with the CBO estimates on which we based Factor 2 in prior fiscal years, the NHEA estimates are for a calendar year. In the rulemaking for FY 2014, many commenters noted that the uncompensated care payments are made for the fiscal year and not on a calendar year basis and requested that CMS normalize the CBO estimate to reflect a fiscal year basis. Specifically, commenters requested that CMS calculate a weighted average of the CBO estimate for October through December 2013 and the CBO estimate for January through September 2014 when determining Factor 2 for FY 2014. We agreed with the commenters that normalizing the estimate to cover FY 2014 rather than CY 2014 would more accurately reflect the rate of uninsurance that hospitals would experience during the FY 2014 payment year. Accordingly, we estimated the rate of uninsurance for FY 2014 by calculating a weighted average of the CBO estimates for CY 2013 and CY 2014 (78 FR 50633). We have continued this weighted average approach in each fiscal year since FY 2014.

We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year more accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, we are proposing to continue to apply the weighted average approach used in past fiscal years in order to estimate the rate of uninsurance for FY 2020. The OACT has certified this estimate of the fiscal year rate of uninsurance to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act.

The calculation of the proposed Factor 2 for FY 2020 using a weighted average of the OACT's projections for CY 2019 and CY 2020 is as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2019: 9.4 percent.
- Percent of individuals without insurance for CY 2020: 9.4 percent.
- Percent of individuals without insurance for FY 2020 (0.25 times 0.094) + (0.75 times 0.094): 9.4 percent $1 - |((0.094 - 0.14)/0.14)| = 1 - 0.3286 = 0.6714$ (67.14 percent).

For FY 2020 and subsequent fiscal years, section 1886(r)(2)(B)(ii) of the Act no longer includes any reduction to the above calculation. Therefore, we are proposing that Factor 2 for FY 2020 will be 67.14 percent.

The proposed FY 2020 uncompensated care amount is $12,643,011,209.74 \times 0.6714 = $8,488,517,726.22.

Proposed FY 2020 Uncompensated Care Amount	$8,488,517,726.22

We are inviting public comments on our proposed methodology for calculating Factor 2 for FY 2020.

c. Calculation of Proposed Factor 3 for FY 2020

(1) General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) The amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, the first year this provision was in effect, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and determined that Worksheet S–10 of the Medicare cost report potentially provides the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on Worksheet S–10 and the completeness of these data, we did not use Worksheet S–10 data to determine Factor 3 for FY 2014, or for FYs 2015, 2016, or 2017. Instead, we believed that the utilization of insured low-income patients, as measured by patient days, would be a better proxy for the costs of hospitals in treating the uninsured and therefore appropriate to use in calculating Factor 3 for these years. Of particular importance in our decision making was the relative newness of Worksheet S–10, which went into effect on May 1, 2010. At the time of the rulemaking for FY 2014, the most recent available cost reports would have been from FYs 2010 and 2011, which were submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. We believed that concerns about the standardization and completeness of the Worksheet S–10 data could be more acute for data collected in the first year of the Worksheet's use (78 FR 50635). In addition, we believed that it would be most appropriate to use data elements that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes) to determine the amount of uncompensated care for purposes of Factor 3 (78 FR 50635). At the time we issued the FY 2014 IPPS/LTCH PPS final rule, we did not believe that the available data regarding uncompensated care from Worksheet S–10 met these criteria and, therefore, we believed they were not reliable enough to use for

determining FY 2014 uncompensated care payments. For FYs 2015, 2016, and 2017, the cost reports used for calculating uncompensated care payments (that is, FYs 2011, 2012, and 2013) were also submitted prior to the time that hospitals were on notice that Worksheet S–10 could be the data source for calculating uncompensated care payments. Therefore, we believed it was also appropriate to use proxy data to calculate Factor 3 for these years. We indicated our belief that Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals were submitting more accurate and consistent data through this reporting mechanism.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38202), we stated that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, hospitals' cost reports from FY 2014 had been publicly available for some time, and CMS had analyses of Worksheet S–10, conducted both internally and by stakeholders, demonstrating that Worksheet S–10 accuracy had improved over time. Analyses performed by MedPAC had already shown that the correlation between audited uncompensated care data from 2009 and the data from the FY 2011 Worksheet S–10 was over 0.80, as compared to a correlation of approximately 0.50 between the audited uncompensated care data and 2011 Medicare SSI and Medicaid days. Based on this analysis, MedPAC concluded that use of Worksheet S–10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs, and that the data on Worksheet S–10 would improve over time as the data are actually used to make payments (81 FR 25090). In addition, a 2007 MedPAC analysis of data from the Government Accountability Office (GAO) and the American Hospital Association (AHA) had suggested that Medicaid days and low-income Medicare days are not an accurate proxy for uncompensated care costs (80 FR 49525).

Subsequent analyses from Dobson/DaVanzo, originally commissioned by CMS for the FY 2014 rulemaking and updated in later years, compared Worksheet S–10 and IRS Form 990 data and assessed the correlation in Factor 3s derived from each of the data sources. Our analyses on balance led us to believe that we had reached a tipping point in FY 2018 with respect to the use of the Worksheet S–10 data. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38201 through 38203) for a complete discussion of these analyses.

We found further evidence for this tipping point when we examined changes to the FY 2014 Worksheet S–10 data submitted by hospitals following the publication of the FY 2017 IPPS/LTCH PPS final rule. In the FY 2017 IPPS/LTCH PPS final rule, as part of our ongoing quality control and data improvement measures for the Worksheet S–10, we referred readers to Change Request 9648, Transmittal 1681, titled ''The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2014 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCHs),'' issued on July 15, 2016 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1681OTN.pdf*). In this transmittal, as part of the process for ensuring complete submission of Worksheet S–10 by all eligible DSH hospitals, we instructed MACs to accept amended Worksheets S–10 for FY 2014 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal stated that, for revisions to be considered, hospitals were required to submit their amended FY 2014 cost report containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than September 30, 2016. For the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19949 through 19950), we examined hospitals' FY 2014 cost reports to see if the Worksheet S–10 data on those cost reports had changed as a result of the opportunity for hospitals to submit revised Worksheet S–10 data for FY 2014. Specifically, we compared hospitals' FY 2014 Worksheet S–10 data as they existed in the first quarter of CY 2016 with data from the fourth quarter of CY 2016. We found that the FY 2014 Worksheet S–10 data had changed over that time period for approximately one quarter of hospitals that receive uncompensated care payments. The fact that the Worksheet S–10 data changed for such a significant number of hospitals following a review of the cost report data they originally submitted and that the revised Worksheet S–10 information is available to be used in determining uncompensated care costs contributed to our belief that we could no longer conclude that alternative data are available that are a better proxy than the Worksheet S–10 data for the costs of subsection (d) hospitals for treating individuals who are uninsured.

We also recognized commenters' concerns that, in using Medicaid days as part of the proxy for uncompensated care, it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid. Because the earliest Medicaid expansions under the Affordable Care Act began in 2014, the 2011, 2012, and 2013 Medicaid days used to calculate uncompensated care payments in FYs 2015, 2016, and 2017 are the latest available data on Medicaid utilization that do not reflect the effects of these Medicaid expansions. Accordingly, if we had used only low-income insured days to estimate uncompensated care in FY 2018, we would have needed to hold the time period of these data constant and use data on Medicaid days from 2011, 2012, and 2013 in order to avoid the risk of any redistributive effects arising from the decision to expand Medicaid in certain States. As a result, we would have been using older data that may provide a less accurate proxy for the level of uncompensated care being furnished by hospitals, contributing to our growing concerns regarding the continued use of low-income insured days as a proxy for uncompensated care costs in FY 2018.

In summary, as we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38203), when weighing the new information regarding the correlation between the Worksheet S–10 data and IRS 990 data that became available to us after the FY 2017 rulemaking in conjunction with the information regarding Worksheet S–10 data and the low-income days proxy that we analyzed as part of our consideration of this issue in prior rulemaking, we determined that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. We also stated that we believe that continued use of Worksheet S–10 will improve the

accuracy and consistency of the reported data, especially in light of CMS' concerted efforts to allow hospitals to review and resubmit their Worksheet S–10 data for past years and the use of trims for potentially aberrant data (82 FR 38207, 38217, and 38218). We also committed to continue to work with stakeholders to address their concerns regarding the accuracy of the reporting of uncompensated care costs through provider education and refinement of the instructions to Worksheet S–10.

For FY 2019, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41413), we continued to monitor the reporting of Worksheet S–10 data in anticipation of using Worksheet S–10 data from hospitals' FY 2014 and FY 2015 cost reports in the calculation of Factor 3. We acknowledged the concerns that had been raised regarding the instructions for Worksheet S–10. In particular, commenters had expressed concerns that the lack of clear and concise line-level instructions prevented accurate and consistent data from being reported on Worksheet S–10. We noted that, in November 2016, CMS issued Transmittal 10, which clarified and revised the instructions for the Worksheet S–10, including the instructions regarding the reporting of charity care charges. Transmittal 10 is available for download on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R10P240.pdf.* In Transmittal 10, we clarified that hospitals may include discounts given to uninsured patients who meet the hospital's charity care criteria in effect for that cost reporting period. This clarification applied to cost reporting periods beginning prior to October 1, 2016, as well as cost reporting periods beginning on or after October 1, 2016. As a result, nothing prohibits a hospital from considering a patient's insurance status as a criterion in its charity care policy. A hospital determines its own financial criteria as part of its charity care policy. The instructions for the Worksheet S–10 set forth that hospitals may include discounts given to uninsured patients, including patients with coverage from an entity that does not have a contractual relationship with the provider, who meet the hospital's charity care criteria in effect for that cost reporting period. In addition, we revised the instructions for the Worksheet S–10 for cost reporting periods beginning on or after October 1, 2016, to provide that charity care charges must be determined in accordance with the hospital's charity care criteria/policy and written off in the cost reporting period, regardless of the date of service.

During the FY 2018 rulemaking, commenters pointed out that, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56963), CMS agreed to institute certain additional quality control and data improvement measures prior to moving forward with incorporating Worksheet S–10 data into the calculation of Factor 3. However, the commenters indicated that, aside from a brief window in 2016 for hospitals to submit corrected data on their FY 2014 Worksheet S–10 by September 30, 2016, and the issuance of revised instructions (Transmittal 10) in November 2016 that are applicable to cost reports beginning on or after October 1, 2016, CMS had not implemented any additional quality control and data improvement measures. We stated in the FY 2018 IPPS/LTCH PPS final rule that we would continue to work with stakeholders to address their concerns regarding the reporting of uncompensated care through provider education and refinement of the instructions to the Worksheet S–10 (82 FR 38206).

On September 29, 2017, we issued Transmittal 11, which clarified the definitions and instructions for uncompensated care, non-Medicare bad debt, non-reimbursed Medicare bad debt, and charity care, as well as modified the calculations relative to uncompensated care costs and added edits to ensure the integrity of the data reported on Worksheet S–10. Transmittal 11 is available for download on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R11p240.pdf.* We further clarified that full or partial discounts given to uninsured patients who meet the hospital's charity care policy or financial assistance policy/uninsured discount policy (hereinafter referred to as Financial Assistance Policy or FAP) may be included on Line 20, Column 1 of Worksheet S–10. These clarifications apply to cost reporting periods beginning on or after October 1, 2013. We also modified the application of the CCR. We specified that the CCR will not be applied to the deductible and coinsurance amounts for insured patients approved for charity care and non-reimbursed Medicare bad debt. The CCR will be applied to the charges for uninsured patients approved for charity care or an uninsured discount, non-Medicare bad debt, and charges for noncovered days exceeding a length of stay limit imposed on patients covered by Medicaid or other indigent care programs.

We also provided another opportunity for hospitals to submit revisions to their Worksheet S–10 data for FY 2014 and FY 2015 cost reports. We refer readers to Change Request 10378, Transmittal 1981, titled ''Fiscal Year (FY) 2014 and 2015 Worksheet S–10 Revisions: Further Extension for All Inpatient Prospective Payment System (IPPS) Hospitals,'' issued on December 1, 2017 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1981OTN.pdf*). In this transmittal, we instructed MACs to accept amended Worksheets S–10 for FY 2014 and FY 2015 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal included the deadlines by which hospitals needed to submit their amended FY 2014 and FY 2015 cost reports containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC, as well as the dates by which MACs must have accepted these data and uploaded the revised cost report to the HCRIS, in order for the data to be considered for purposes of the FY 2019 rulemaking.

(2) Background on the Methodology Used To Calculate Factor 3 for FY 2019

Section 1886(r)(2)(C) of the Act governs both the selection of the data to be used in calculating Factor 3, and also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for such hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and

final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2017 IPPS/LTCH PPS final rule, in order to mitigate undue fluctuations in the amount of uncompensated care payments to hospitals from year to year and smooth over anomalies between cost reporting periods, we finalized a policy of calculating a hospital's share of uncompensated care based on an average of data derived from three cost reporting periods instead of one cost reporting period. As explained in the preamble to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56957 through 56959), instead of determining Factor 3 using data from a single cost reporting period as we did in FY 2014, FY 2015, and FY 2016, we used data from three cost reporting periods (Medicaid data for FYs 2011, 2012, and 2013 and SSI days from the three most recent available years of SSI utilization data (FYs 2012, 2013, and 2014)) to compute Factor 3 for FY 2017. Furthermore, instead of determining a single Factor 3 as we had done since the first year of the uncompensated care payment in FY 2014, we calculated an individual Factor 3 for each of the three cost reporting periods, which we then averaged by the number of cost reporting years with data to compute the final Factor 3 for a hospital. Under this policy, if a hospital had merged, we would combine data from both hospitals for the cost reporting periods in which the merger was not reflected in the surviving hospital's cost report data to compute Factor 3 for the surviving hospital. Moreover, to further reduce undue fluctuations in a hospital's uncompensated care payments, if a hospital filed multiple cost reports beginning in the same fiscal year, we combined data from the multiple cost reports so that a hospital could have a Factor 3 calculated using more than one cost report within a cost reporting period. We codified these changes for FY 2017 by amending the regulation at § 412.106(g)(1)(iii)(C).

As we stated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41414), with the additional steps we had taken to ensure the accuracy and consistency of the data reported on Worksheet S–10 since the publication of the FY 2018 IPPS/LTCH PPS final rule, we continued to believe that we can no longer conclude that alternative data to the Worksheet S–10 are currently available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Similarly, the actions that we have taken to improve the accuracy and consistency of the Worksheet S–10 data, including the opportunity for hospitals to resubmit Worksheet S–10 data for FY 2015, led us to conclude that there are no alternative data to the Worksheet S–10 data currently available for FY 2015 that are a better proxy for the costs of subsection (d) hospitals for treating uninsured individuals. As such, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41428), we finalized our proposal to advance the time period of the data used in the calculation of Factor 3 forward by 1 year and to use data from FY 2013, FY 2014, and FY 2015 cost reports to determine Factor 3 for FY 2019. For the reasons we described earlier, we stated that we continue to believe it is inappropriate to use Worksheet S–10 data for periods prior to FY 2014. Rather, for cost reporting periods prior to FY 2014, we indicated that we believe it is appropriate to continue to use low-income insured days. Accordingly, with a time period that includes 3 cost reporting years consisting of FY 2013, FY 2014, and FY 2015, we used Worksheet S–10 data for the FY 2014 and FY 2015 cost reporting periods and the low-income insured days proxy data for the earliest cost reporting period. As in previous years, in order to perform this calculation for the FY 2019 final rule, we drew three sets of data (1 year of Medicaid utilization data and 2 years of Worksheet S–10 data) from the most recent available HCRIS extract, which was the June 30, 2018 update of HCRIS, due to the unique circumstances related to the impact of the hurricanes in 2017 (Harvey, Irma, Maria, and Nate) and the extension of the deadline to resubmit Worksheet S–10 data through January 2, 2018, and the subsequent impact on the MAC review timeline (83 FR 41421).

Accordingly, for FY 2019, in addition to the Worksheet S–10 data for FY 2014 and FY 2015, we used Medicaid days from FY 2013 cost reports and FY 2016 SSI ratios. We noted that cost report data from Indian Health Service and Tribal hospitals are included in HCRIS beginning in FY 2013 and no longer need to be incorporated from a separate data source. We also continued the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers. In addition, we continued the policies that were finalized in the FY 2018 IPPS/LTCH PPS final rule to address technical considerations related to the calculation of Factor 3 and the incorporation of Worksheet S–10 data (82 FR 38213 through 38220). In that final rule, we adopted a policy, for purposes of calculating Factor 3, under which we annualize Medicaid days data and uncompensated care cost data reported on the Worksheet S–10 if a hospital's cost report does not equal 12 months of data. As in FY 2018, for FY 2019, we did not annualize SSI days because we do not obtain these data from hospital cost reports in HCRIS. Rather, we obtained these data from the latest available SSI ratios posted on the Medicare DSH homepage (*https://www.cms.gov/Medicare/Medicare-fee-for-service-payment/AcuteInpatientPPS/dsh.html*), which were aggregated at the hospital level and did not include the information needed to determine if the data should be annualized. To address the effects of averaging Factor 3s calculated for 3 separate fiscal years, we continued to apply a scaling factor to the Factor 3 values of all DSH eligible hospitals such that total uncompensated care payments are consistent with the estimated amount available to make uncompensated care payments for the applicable fiscal year. With respect to the incorporation of data from Worksheet S–10, we indicated that we believe that the definition of uncompensated care adopted in FY 2018 is still appropriate because it incorporates the most commonly used factors within uncompensated care as reported by stakeholders, including charity care costs and non-Medicare bad debt costs, and correlates to Line 30 of Worksheet S–10. Therefore, for purposes of calculating Factor 3 and uncompensated care costs in FY 2019, we again defined ''uncompensated care'' as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29).

We noted that we were discontinuing the policy finalized in the FY 2017 IPPS/LTCH PPS final rule concerning multiple cost reports beginning in the same fiscal year (81 FR 56957). Under this policy, we would first combine the data across the multiple cost reports before determining the difference between the start date and the end date to determine if annualization was needed. This policy was developed in response to commenters' concerns regarding the unique circumstances of

hospitals that file cost reports that are shorter or longer than 12 months. As we explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56957 through 56959) and in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19953), we believed that, for hospitals that file multiple cost reports beginning in the same year, combining the data from these cost reports had the benefit of supplementing the data of hospitals that filed cost reports that are less than 12 months, such that the basis of their uncompensated care payments and those of hospitals that filed full-year 12-month cost reports would be more equitable. As we stated in the FY 2019 IPPS/LTCH PPS proposed and final rules, we now believe that concerns about the equitability of the data used as the basis of hospital uncompensated care payments are more thoroughly addressed by the policy finalized in the FY 2018 IPPS/LTCH PPS final rule, under which CMS annualizes the Medicaid days and uncompensated care cost data of hospital cost reports that do not equal 12 months of data. Based on our experience, we stated that we believe that in many cases where a hospital files two cost reports beginning in the same fiscal year, combining the data across multiple cost reports before annualizing would yield a similar result to choosing the longer of the two cost reports and then annualizing the data if the cost report is shorter or longer than 12 months. Furthermore, even in cases where a hospital files more than one cost report beginning in the same fiscal year, it is not uncommon for one of those cost reports to span exactly 12 months. In this case, if Factor 3 is determined using only the full 12-month cost report, annualization would be unnecessary as there would already be 12 months of data. Therefore, for FY 2019, we stated that we believed it was appropriate to eliminate the additional step of combining data across multiple cost reports if a hospital filed more than one cost report beginning in the same fiscal year. Instead, for purposes of calculating Factor 3, we used data from the cost report that is equivalent to 12 months or, if no such cost report existed, the cost report that was closest to 12 months, and annualized the data. Furthermore, we acknowledged that, in rare cases, a hospital may have more than one cost report beginning in one fiscal year, where one report also spans the entirety of the following fiscal year, such that the hospital has no cost report beginning in that fiscal year. For instance, a hospital's cost reporting period may have started towards the end of FY 2012 but cover the duration of FY 2013. In these rare situations, we would use data from the cost report that spans both fiscal years in the Factor 3 calculation for the latter fiscal year as the hospital would already have data from the preceding cost report that could be used to determine Factor 3 for the previous fiscal year.

In FY 2019, we also continued to apply statistical trims to anomalous hospital CCRs using a similar methodology to the one adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38217 through 38219), where we stated our belief that, just as we apply trims to hospitals' CCRs to eliminate anomalies when calculating outlier payments for extraordinarily high cost cases (§ 412.84(h)(3)(ii)), it is appropriate to apply statistical trims to the CCRs on Worksheet S–10, Line 1, that are considered anomalies. Specifically, § 412.84(h)(3)(ii) states that the Medicare contractor may use a statewide CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, the CCR ''ceiling''). The geometric means for purposes of the Worksheet S–10 trim of CCRs and for purposes of § 412.84(h)(3)(ii) are separately calculated annually by CMS and published in the applicable sections of the proposed and final IPPS rules each year. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41415) for a detailed description of the CCR trim methodology for purposes of the Worksheet S–10 trim of CCRs, which included calculating 3 standard deviations above the national geometric mean CCR for each of the applicable cost report years (FY 2014 and FY 2015) that were part of the Factor 3 methodology for FY 2019.

Similar in concept to the policy that we adopted for FY 2018, for FY 2019, we stated that we continued to believe that uncompensated care costs that represent an extremely high ratio of a hospital's total operating expenses (such as the ratio of 50 percent used in the FY 2018 IPPS/LTCH PPS final rule) may be potentially aberrant, and that using the ratio of uncompensated care costs to total operating costs to identify potentially aberrant data when determining Factor 3 amounts has merit. We noted that we had instructed the MACs to review situations where a hospital has an extremely high ratio of uncompensated care costs to total operating costs with the hospital, but also indicated that we did not intend to make the MACs' review protocols public (83 FR 41416). Similarly, we believe that situations where there were extremely large dollar increases or decreases in a hospital's uncompensated care costs when it resubmitted its FY 2014 Worksheet S–10 or FY 2015 Worksheet S–10 data, or when the data it had previously submitted were reprocessed by the MAC, may reflect potentially aberrant data and warrant further review. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20399), we noted that our calculation of Factor 3 for the final rule would be contingent on the results of the ongoing MAC reviews of hospitals' Worksheet S–10 data, and in the event those reviews necessitate supplemental data edits, we would incorporate such edits in the final rule for the purpose of correcting aberrant data. After the completion of the MAC reviews, we did not incorporate any additional edits to the Worksheet S–10 data that we did not propose in the FY 2019 IPPS/LTCH PPS proposed rule. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41416) for a detailed discussion of our policies for trimming aberrant data. In brief summary, in cases where a hospital's uncompensated care costs for FY 2014 or FY 2015 were an extremely high ratio of its total operating costs, and the hospital could not justify the amount it reported, we determined the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and applied that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs. For example, if the FY 2015 cost report was determined to include potentially aberrant data, data from the FY 2016 cost report would be used for the ratio calculation. In this case, the hospital's uncompensated care costs for FY 2015 would be trimmed by multiplying its FY 2015 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2016 cost report to calculate an estimate of the hospital's uncompensated care costs for FY 2015 for purposes of determining Factor 3 for FY 2019.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41416), for Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and all-inclusive rate providers, we continued the policy we first adopted for FY 2018 of substituting data regarding FY 2013 low-income insured days for the Worksheet S–10 data when determining Factor 3. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38209), the use of data from Worksheet S–10 to calculate the uncompensated care amount for Indian Health Service and Tribal hospitals may jeopardize

these hospitals' uncompensated care payments due to their unique funding structure. With respect to Puerto Rico hospitals, we indicated that we continue to agree with concerns raised by commenters that the uncompensated care data reported by these hospitals need to be further examined before the data are used to determine Factor 3 (82 FR 38209). Finally, we acknowledged that the CCRs for all-inclusive rate providers are potentially erroneous and still in need of further examination before they can be used in the determination of uncompensated care amounts for purposes of Factor 3 (82 FR 38212). For the reasons described earlier related to the impact of the Medicaid expansion beginning in FY 2014, we stated that we also continue to believe that it is inappropriate to calculate a Factor 3 using FY 2014 and FY 2015 low-income insured days. Because we did not believe it was appropriate to use the FY 2014 or FY 2015 uncompensated care data for these hospitals and we also did not believe it was appropriate to use the FY 2014 or FY 2015 low-income insured days, we stated that the best proxy for the costs of Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and all-inclusive rate providers for treating the uninsured continues to be the low-income insured days data for FY 2013. Accordingly, for these hospitals, we determined Factor 3 only on the basis of low-income insured days for FY 2013. We stated our belief that this approach was appropriate as the FY 2013 data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. In addition, because we continued to use 1 year of insured low-income patient days as a proxy for uncompensated care and residents of Puerto Rico are not eligible for SSI benefits, we continued to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

Therefore, for FY 2019, we computed Factor 3 for each hospital by—

Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2013 cost report data and the FY 2016 SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days);

Step 2: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data;

Step 3: Calculating Factor 3 based on the FY 2015 Worksheet S–10 data; and

Step 4: Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2013, FY 2014, and FY 2015 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3 (or for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and all-inclusive rate providers, using the Factor 3 value from Step 1).

We also amended the regulations at § 412.106(g)(1)(iii)(C) by adding a new paragraph (5) to reflect the above methodology for computing Factor 3 for FY 2019.

In the FY 2019 IPPS/LTCH PPS final rule, we noted that if a hospital does not have both Medicaid days for FY 2013 and SSI days for FY 2016 available for use in the calculation of Factor 3 in Step 1, we would consider the hospital not to have data available for the fiscal year, and would remove that fiscal year from the calculation and divide by the number of years with data. A hospital would be considered to have both Medicaid days and SSI days data available if it reported zero days for either component of the Factor 3 calculation in Step 1. However, if a hospital was missing data due to not filing a cost report in one of the applicable fiscal years, we would divide by the remaining number of fiscal years.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41417), we noted that we did not make any proposals with respect to the development of Factor 3 for FY 2020 and subsequent fiscal years. However, we noted that the above methodology would have the effect of fully transitioning the incorporation of data from Worksheet S–10 into the calculation of Factor 3 if used in FY 2020, and therefore, the use of low-income insured days would be phased out by FY 2020 if the same methodology were to be proposed and finalized for that year. We also indicated that it was possible that when we examine the FY 2016 Worksheet S–10 data, we might determine that the use of multiple years of Worksheet S–10 data is no longer necessary in calculating Factor 3 for FY 2020. We stated that, given the efforts hospitals have already undertaken with respect to reporting their Worksheet S–10 data and the subsequent reviews by the MACs that had already been conducted prior to the development of the FY 2019 IPPS/LTCH PPS final rule, along with additional review work that might take place following the issuance of the FY 2019 final rule, we might consider using 1 year of Worksheet S–10 data as the basis for calculating Factor 3 for FY 2020.

For new hospitals that did not have data for any of the three cost reporting periods used in the Factor 3 calculation for FY 2019, we continued to apply the new hospital policy finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50643). That is, the hospital would not receive either interim empirically justified Medicare DSH payments or interim uncompensated care payments. However, if the hospital is later determined to be eligible to receive empirically justified Medicare DSH payments based on its FY 2019 cost report, the hospital would also receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2019 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2015 cost reports for all DSH eligible hospitals (that is, the most recent year of the 3-year time period used in the development of Factor 3 for FY 2019). We noted that, given the time period of the data used to calculate Factor 3, any hospitals with a CCN established after October 1, 2015, would be considered new and subject to this policy.

(3) Proposed Methodology for Calculating Factor 3 for FY 2020

(a) Proposal to Use of Audited FY 2015 Data

Since the publication of the FY 2019 IPPS/LTCH PPS final rule, we have continued to monitor the reporting of Worksheet S–10 data in order to determine the most appropriate data to use in the calculation of Factor 3 for FY 2020. As stated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41424), due to the overwhelming feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we expected audits of the Worksheet S–10 to begin in the Fall of 2018. The audit protocol instructions were still under development at the time of the FY 2019 IPPS/LTCH PPS final rule; yet, we noted the audit protocols would be provided to the MACs in advance of the audit. Once the audit protocol instructions were complete, we began auditing the Worksheet S–10 data for selected hospitals in the Fall of 2018 so that the audited uncompensated care data from these hospitals would be available in time for use in this FY 2020 proposed rule. We chose to audit 1 year of data (that is, FY 2015) in order to maximize the available audit resources and not spread those audit resources over multiple years, potentially diluting their effectiveness. We chose to focus the audit on the FY 2015 cost reports primarily because this was the most

recent year of data that we had broadly allowed to be resubmitted by hospitals, and many hospitals had already made considerable efforts to amend their FY 2015 reports for the FY 2019 rulemaking. We also considered that we had previously used the FY 2015 data as part of the calculation of the FY 2019 uncompensated care payments; therefore, the data had previously been subject to public comment and scrutiny.

Given that we have conducted audits of the FY 2015 Worksheet S–10 data and have previously used the FY 2015 data to determine uncompensated care payments, and the fact that the FY 2015 data are the most recent data that we have allowed to be resubmitted to date, we believe that, on balance, the FY 2015 Worksheet S–10 data are the best available data to use for calculating Factor 3 for FY 2020. However, as discussed in more detail later in the next section, an alternative we also considered is the use of FY 2017 data. We are seeking public comments on this alternative and, based on the public comments we receive, could adopt it in the FY 2020 final rule.

We recognize that, in FY 2019, we used 3 years of data in the calculation of Factor 3 in order to smooth over anomalies between cost reporting periods and to mitigate undue fluctuations in the amount of uncompensated care payments from year to year. However, we believe that, for FY 2020, mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result, which is counter to our original goal in using 3 years of data. To the extent that the audited FY 2015 data for a hospital are relatively different from its unaudited FY 2014 data and/or its unaudited FY 2016 data, we potentially would be diluting the effect of our considerable auditing efforts and introducing unnecessary variability into the calculation if we continued to use 3 years of data to calculate Factor 3. For example, approximately 10 percent of audited hospitals have more than a $20 million difference between their audited FY 2015 data and their unaudited FY 2016 data.

Accordingly, we are proposing to use a single year of Worksheet S–10 data from FY 2015 cost reports to calculate Factor 3 in the FY 2020 methodology. We note that the proposed uncompensated care payments to hospitals whose FY 2015 Worksheet S–10 data were audited represent approximately half of the proposed total uncompensated care payments for FY 2020. For purposes of this FY 2020 proposed rule, we have used the most recent available HCRIS extract available, which is the HCRIS data updated through February 15, 2019. We expect to use the March 2019 update of HCRIS for the final rule.

(b) Alternative Considered To Use FY 2017 Data

Although we are proposing to use Worksheet S–10 data from the FY 2015 cost reports, we acknowledge that some hospitals have raised concerns regarding some of the adjustments made to the FY 2015 cost reports following the audits of these reports (for example, adjustments made to Line 22 of Worksheet S–10). These hospitals contend that there are issues regarding the instructions in effect for FY 2015, especially compared to the reporting instructions that were effective for cost reporting periods beginning on or after October 1, 2016, and some of these adjustments would not have been made if CMS had chosen as an alternative to audit the FY 2017 reports.

Accordingly, we are seeking public comments on whether the changes in the reporting instructions between the FY 2015 cost reports and the FY 2017 cost reports have resulted in a better common understanding among hospitals of how to report uncompensated care costs and improved relative consistency and accuracy across hospitals in reporting these costs. We also are seeking public comments on whether, due to the changes in the reporting instructions, we should use a single year of uncompensated care cost data from the FY 2017 reports, instead of the FY 2015 reports, to calculate Factor 3 for FY 2020. We note that we are not proposing to use FY 2016 reports because the reporting instructions for that year were similar to the reporting instructions for the FY 2015 reports. If, based on the public comments received, we were to adopt a final policy in which we use Worksheet S–10 data from the FY 2017 cost reports to determine Factor 3 for FY 2020, we would also expect to use the March 2019 update of HCRIS for the final rule.

Under the alternative considered on which we are seeking public comment, the FY 2017 Worksheet S–10 data would be used instead of the FY 2015 Worksheet S–10 data, but, in general, the proposed Factor 3 methodology would be unchanged. The limited circumstances where the methodology would need to differ from the proposed methodology using FY 2015 data, if we were to adopt the alternative of using FY 2017 data in the final rule based on the public comments received, are outlined in section IV.F.4.c.(3)(d) of the preamble of this proposed rule (Methodological Considerations for Calculating Factor 3). If an aspect of the proposed methodology described below does not specifically indicate that we would modify it under the alternative considered, that aspect of the methodology would be unchanged, regardless of whether we use FY 2015 data or FY 2017 data. We note that we are providing all of the same public information regarding the alternative considered, including the Factor 3 values for each hospital and the impact information, that we are providing for our proposal to use FY 2015 data.

(c) Proposed Definition of ''Uncompensated Care''

We continue to believe that the definition of ''uncompensated care'' first adopted in FY 2018 when we started to incorporate data from Worksheet S–10 into the determination of Factor 3 and used again in FY 2019 is appropriate, as it incorporates the most commonly used factors within uncompensated care as reported by stakeholders, namely, charity care costs and bad debt costs, and correlates to Line 30 of Worksheet S–10. Therefore, we are proposing that, for purposes of determining uncompensated care costs and calculating Factor 3 for FY 2020, ''uncompensated care'' would continue to be defined as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29).

(d) Methodological Considerations for Calculating Factor 3

For FY 2020, we are proposing to continue the merger policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020). In addition, we are proposing to continue the policy that was finalized in the FY 2018 IPPS/LTCH PPS final rule of annualizing uncompensated care cost data reported on the Worksheet S–10 if a hospital's cost report does not equal 12 months of data.

We are proposing to modify the new hospital policy first adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50643) and continued through the FY 2019 IPPS/LTCH PPS final rule (83 FR 41417), for new hospitals that do not have data for the cost reporting period(s) used in the proposed Factor 3 calculation. For FY 2020, new hospitals that are eligible for Medicare DSH would receive interim empirically justified DSH payments. Generally, new hospitals do not yet have available data to project their eligibility for DSH

payments because there is a lag until the SSI ratio and the Medicaid ratio become available. However, we note that there are some new hospitals (that is, hospitals with CCNs established after October 1, 2015) that have a preliminary projection of being eligible for DSH payments based on their most recent available DSH percentages. Because these hospitals do not have a FY 2015 cost report to use in the Factor 3 calculation and the projection of eligibility for DSH payments is still preliminary, we are proposing that the MAC would make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2020 cost report. If the hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2020, the hospital would receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2020 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2015 cost reports for all DSH-eligible hospitals. This denominator would be the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals, excluding Puerto Rico hospitals and Indian Health Service and Tribal hospitals. The new hospital would not receive interim uncompensated care payments before cost report settlement because we would have no FY 2015 uncompensated care data on which to determine what those interim payments should be. We note that, given the time period of the data we are proposing to use to calculate Factor 3, any hospitals with a CCN established on or after October 1, 2015, would be considered new and subject to this policy. However, under the alternative policy considered of using FY 2017 data, we would modify the new hospital policy, such that any hospital with a CCN established on or after October 1, 2017, would be considered new and subject to this policy with conforming changes to provide for the use of FY 2017 uncompensated care data.

We have received questions regarding the new hospital policy for new Puerto Rico hospitals. In FY 2018 and FY 2019, Factor 3 for all Puerto Rico hospitals, including new Puerto Rico hospitals, was based on the low-income insured proxy data. Under this approach, the MAC will calculate a Factor 3 for new Puerto Rico hospitals at cost report settlement for the applicable fiscal year using the Medicaid days from the hospital's cost report and the SSI day proxy (that is, 14 percent of the hospital's Medicaid days) divided by the low-income insured proxy data denominator that was established for that fiscal year. For FY 2020, we are proposing that Puerto Rico hospitals that do not have a FY 2013 report would be considered new hospitals and would be subject to the proposed new hospital policy, as discussed above. Specifically, the numerator would be the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2020 cost report and the denominator would be the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals. We believe this notice of proposed rulemaking provides sufficient time for all new hospitals to take the steps necessary to ensure that their uncompensated care costs for FY 2020 are accurately reported on their FY 2020 Worksheet S–10. In addition, we expect MACs to review FY 2020 reports from new hospitals, as necessary, which will address past commenters' concerns regarding the need for further review of Puerto Rico hospitals' uncompensated care data before the data are used to determine Factor 3. Therefore, we believe the uncompensated care costs reported on their FY 2020 Worksheet S–10 are the best available and appropriate data to use to calculate Factor 3 for new Puerto Rico hospitals. This proposed would also allow our new hospital policy to be more uniform, given that Worksheet S–10 would be the source of the uncompensated care cost data across all new hospitals.

For Indian Health Service and Tribal hospitals and subsection (d) Puerto Rico hospitals that have a FY 2013 cost report, we are proposing to adapt the policy first adopted for the FY 2018 rulemaking regarding FY 2013 low-income insured days when determining Factor 3. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38209), the use of data from Worksheet S–10 to calculate the uncompensated care amount for Indian Health Service and Tribal hospitals may jeopardize these hospitals' uncompensated care payments due to their unique funding structure. With respect to Puerto Rico hospitals that would not be subject to the proposed new hospital policy, we continue to agree with concerns raised by commenters that the uncompensated care data reported by these hospitals need to be further examined before the data are used to determine Factor 3 (82 FR 38209). Accordingly, for these hospitals, we are proposing to determine Factor 3 based on Medicaid days from FY 2013 and the most recent update of SSI days. The aggregate amount of uncompensated care that is used in the Factor 3 denominator for these hospitals would continue to be based on the low-income patient proxy; that is, the aggregate amount of uncompensated care determined for all DSH eligible hospitals using the low-income insured days proxy. We believe this approach is appropriate because the FY 2013 data reflect the most recent available information regarding these hospitals' Medicaid days before any expansion of Medicaid. At the time of development of this proposed rule, for modeling purposes, we computed Factor 3 for these hospitals using FY 2013 Medicaid days and the most recent available FY 2017 SSI days. In addition, because we are continuing to use 1 year of insured low-income patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we are proposing to continue to use a proxy for SSI days for Puerto Rico hospitals, consisting of 14 percent of a hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41417), we noted that further examination of the CCRs for all-inclusive rate providers was necessary before we considered incorporating Worksheet S–10 into the Factor 3 calculation for these hospitals. We have examined the CCRs from the FY 2015 cost reports and believe the risk that all-inclusive rate providers will have aberrant CCRs and, consequently, aberrant uncompensated care data, is mitigated by the proposal to apply trim methodologies for potentially aberrant uncompensated care costs for all hospitals. Therefore, we believe it is no longer necessary to propose specific Factor 3 policies for all-inclusive rate providers.

Because we are proposing to use 1 year of cost report data, as opposed to averaging 3 cost report years, it is also no longer necessary to propose to apply a scaling factor to the Factor 3 of all DSH eligible hospitals similar to the scaling factor that was finalized in FY 2018 IPPS/LTCH PPS final rule (82 FR 38214) and also applied in the FY 2019 IPPS/LTCH PPS final rule. The primary purpose of the scaling factor was to account for the averaging effect of the use of 3 years of data on the Factor 3 calculation.

However, we are proposing to continue certain other policies finalized

in the FY 2019 IPPS/LTCH PPS final rule, specifically: (1) For providers with multiple cost reports, beginning in the same fiscal year, using the longest cost report and annualizing Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (2) in the rare case where a provider has multiple cost reports, beginning in the same fiscal year, but one report also spans the entirety of the following fiscal year, such that the hospital has no cost report for that fiscal year, using the cost report that spans both fiscal years for the latter fiscal year; and (3) applying statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs reported on the Worksheet S–10. Thus, if a hospital's uncompensated care costs for FY 2015 are an extremely high ratio of its total operating costs, and the hospital cannot justify the amount it reported, we are proposing to determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs. For example, if the FY 2015 cost report is determined to include potentially aberrant data, data from the FY 2016 cost report would be used for the ratio calculation. In this case, similar to the trim methodology used for FY 2019, the hospital's uncompensated care costs for FY 2015 would be trimmed by multiplying its FY 2015 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2016 cost report to calculate an estimate of the hospital's uncompensated care costs for FY 2015 for purposes of determining Factor 3 for FY 2020.

In support of the alternative policy considered of using uncompensated care data from FY 2017 and to improve the quality of the Worksheet S–10 data generally, we are currently in a process of outreach to hospitals related to potentially aberrant data reported in their FY 2017 cost reports. For example, a significant positive or negative difference in the percent of total uncompensated care costs to total operating costs when comparing the hospital's FY 2015 cost report to its FY 2017 cost report may indicate potentially aberrant data. While hospitals may see uncompensated care cost fluctuations from year to year, if a hospital experiences a significant change compared to other comparable hospitals, this could be an indication of potentially aberrant data. A hospital with such changes would have the opportunity to justify its reporting fluctuation to the MAC and, if necessary, to amend its FY 2017 cost report. If a hospital's FY 2017 cost report remains unchanged without an acceptable response or explanation from the provider, under the alternative policy considered, we would trim the data in the provider's FY 2017 cost report using data from the provider's FY 2015 cost report in order to determine Factor 3 for purposes of the final rule.

While we expect all providers will have FY 2017 cost reports in HCRIS by the time that any data would be taken from HCRIS for the final rule, if such data are not reflected in HCRIS for an unforeseen reason unrelated to any inappropriate action or improper reporting on the part of the hospital, we would substitute the Worksheet S–10 data from the FY 2015 cost report for the data from the FY 2017 cost report.

Similar to the process used in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38217 through 38218) and the FY 2019 IPPS/LTCH PPS (83 FR 41415 and 41416) for trimming CCRs, in this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing the following steps:

Step 1: Remove Maryland hospitals. In addition, we would remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

Step 2: For FY 2015 cost reports, calculate a CCR ''ceiling'' with the following data: For each IPPS hospital that was not removed in Step 1 (including non-DSH eligible hospitals), we would use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report would be selected.) The ceiling would be calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR. (For this proposed rule, this trim would remove 8 hospitals that have a CCR above the calculated ceiling of 0.925 for FY 2015 cost reports.) (Under the alternative policy considered, the trim would remove 13 hospitals that have a CCR above the calculated ceiling of 0.942 for FY 2017 cost reports.)

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for FY 2015 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total inpatient discharges and outpatient visits from Worksheet S–3, Part I, Line 14, Column 14.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals with a CCR for FY 2015 greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR ''ceiling''). For this proposed rule, the statewide average CCR would therefore be applied to 8 hospitals, of which 4 hospitals have FY 2015 Worksheet S–10 data. (Under the alternative policy considered, the statewide average CCR would be applied to 13 hospitals, of which 5 hospitals have FY 2017 Worksheet S–10 data.)

For providers that did not report a CCR on Worksheet S–10, Line 1, we would assign them the statewide average CCR in step 4.

After applying the applicable trims to a hospital's CCR as appropriate, we are proposing that we would calculate a hospital's uncompensated care costs for the applicable fiscal year as being equal to Line 30, which is the sum of Line 23, Column 3, and Line 29 determined using the hospital's CCR or the statewide average CCR (urban or rural), if applicable.

Therefore, for FY 2020, we are proposing to compute Factor 3 for each hospital by—

Step 1: Selecting the provider's longest cost report from its Federal fiscal year (FFY) 2015 cost reports. (Alternatively, in the rare case when the provider has no FFY 2015 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2015 time period, the previous Federal fiscal year cost report would be used in this step.)

Step 2: Annualizing the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combining annualized uncompensated care costs for hospitals that merged.

Step 4: Calculating Factor 3 for Indian Health Service and Tribal hospitals and Puerto Rico hospitals using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the

hospital's FY 2013 Medicaid days). The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals.

Step 5: Calculating Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2015 cost report data (from Step 3). The hospitals for which Factor 3 was calculated in Step 4 are excluded from this calculation.

We also are proposing to amend the regulations at § 412.106(g)(1)(iii)(C) by adding a new paragraph (*6*) to reflect the above proposed methodology for computing Factor 3 for FY 2020.

We note that, if a hospital does not have Worksheet S–10 data for FY 2015 and the hospital is not a new hospital (that is, its CCN was established before October 1, 2015) nor has the rare case of no FY 2015 cost report, we are proposing to apply the steps above with uncompensated care costs of zero for the hospital. In addition, if, in the course of the Worksheet S–10 reviews by MACs, a hospital is unable to provide sufficient documentation or is unwilling to justify its cost report, which subsequently results in the hospital's Worksheet S–10 being adjusted to zero, we also are proposing to use the above steps to calculate Factor 3. We recognize that, under this proposal, these hospitals would be treated as having reported no uncompensated care costs on the Worksheet S–10 for FY 2015, which would result in their not receiving uncompensated care payments for FY 2020. However, we believe this proposal is equitable to other hospitals because all short-term acute care hospitals are required to report Worksheet S–10 and must maintain sufficient documentation to support the information reported. In addition, hospitals have been on notice since the beginning of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, we have previously given hospitals the opportunity to amend their Worksheet S–10 for FY 2015 cost reports (or to submit a Worksheet S–10 for FY 2015 if none had been submitted previously).

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with both the FY 2020 IPPS/LTCH PPS proposed rule and final rule, we will publish on the CMS website a table listing Factor 3 computed using both the proposed methodology and the potential alternative methodology for all hospitals that we estimate would receive empirically justified Medicare DSH payments in FY 2020 (that is, those hospitals that would receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a Medicare DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. We note that, at the time of development of this proposed rule, the FY 2017 SSI ratios were available. Accordingly, for purposes of this proposed rule, we have computed Factor 3 for Indian Health Service and Tribal hospitals and Puerto Rico hospitals using the most recent available data regarding SSI days from the FY 2017 SSI ratios. We also will publish in the supplemental data file a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital.

Hospitals have 60 days from the date of public display of this FY 2020 IPPS/LTCH PPS proposed rule to review the table and supplemental data file published on the CMS website in conjunction with the proposed rule and to notify CMS in writing of any inaccuracies. Comments that are specific to the information included in the table and supplemental data file can be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov.* We will address these comments as appropriate in the table and the supplemental data file that we publish on the CMS website in conjunction with the publication of the FY 2020 IPPS/LTCH PPS final rule. After the publication of the FY 2020 IPPS/LTCH PPS final rule, hospitals will have until August 31, 2019, to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with the final rule. Comments may be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov* through August 31, 2019, and any changes to Factor 3 will be posted on the CMS website prior to October 1, 2019.

We are inviting public comments on our proposed methodology for calculating Factor 3 for FY 2020, including, but not limited to, our proposed use of the FY 2015 Worksheet S–10 data and the alternative policy considered of using the FY 2017 Worksheet S–10 data instead of the FY 2015 Worksheet S–10 data.

5. Request for Public Comments on Ways To Reduce Provider Reimbursement Review Board (PRRB) Appeals Related to a Hospital's Medicaid Fraction Used in the Disproportionate Share Hospital (DSH) Payment Adjustment Calculation

As part of our ongoing efforts to reduce regulatory burden on providers, we are examining the backlog of appeals cases at the Provider Reimbursement Review Board (PRRB). A large number of appeals before the PRRB relate to the calculation of a hospital's disproportionate patient percentage (DPP) used in the calculation of the DSH payment adjustment. (We refer readers to section IV.F. 1. of the preamble of this proposed rule for a discussion of the calculation of a hospitals DPP.) Many of these appeals before the PRRB focus on the calculation of a hospital's Medicaid fraction, which is one of the two fractions comprising the DPP, particularly the data used to determine an individual's Medicaid eligibility in the calculation. Specifically, it is possible that updated data on Medicaid eligibility are available following cost report submission. As a result, many hospitals annually appeal their cost reports to the PRRB in an effort to try and use updated State Medicaid eligibility data to calculate the Medicaid fraction. We believe it is in both CMS' and the providers' interest to seek a solution to issues related to the Medicaid fraction that appear to have led to a large volume and backlog of PRRB appeals. Therefore, we believe it is appropriate to explore options that may prevent the need for such appeals. We note that the Provider Reimbursement Review Board Rules, Version 2.0, August 29, 2018, contain revisions in Rules 46 and 47 pertaining to ''Withdrawal of an Appeal or Issue Within an Appeal'' and ''Reinstatement'', respectively. These changes may lower the number of tracked PRRB appeals. In exploring possible solutions, we are concerned about balancing the competing interests of administrative finality, ease of implementation for both CMS and providers, and the use of the most appropriate data.

We believe one such solution might be to develop regulations governing the timing of the data for determining Medicaid eligibility, somewhat similar to our existing policy on entitlement to SSI benefits which is determined at a specific time. For more information on this policy, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50276). Under this possible solution, a provider would submit a cost report

with Medicaid days based on the best available Medicaid eligibility data at the time of filing and could request a ''reopening'' when the cost report is settled without filing an appeal. CMS would issue directives to the MACs requiring them to reopen those cost reports for this issue at a specific time and set a realistic period during which the provider could submit updated data. This would be an expansion of the preamble instructions finalized in the CY 2016 OPPS/ASC final rule with comment period issued on November 13, 2015 (80 FR 70563 and 70564) which requires the MACs to accept one amended cost report submitted within 12 months after the due date of the cost report solely for the purpose of revising Medicaid days. (We note that an amendment of the cost report is initiated by the provider prior to final settlement of the cost report, while a reopening of the cost report occurs after final settlement and can be requested by the provider or initiated by the MAC.) Under this possible expansion, we would require MACs to reopen cost reports for the purpose of revising the Medicaid fraction near the end of the 3-year reopening window and use the Medicaid data at that time to settle the cost report. We believe the 3 years of the reopening period could provide adequate time to update the Medicaid data used to determine an individual's Medicaid eligibility for purposes of calculating a hospital's Medicaid fraction. However, we are generally interested in public comments on using reopenings as a mechanism to use updated Medicaid eligibility data and reduce the filing of PRRB appeals—in particular, the optimal time for review of data to occur taking into account the hospital's desire to receive accurate payment and CMS' and the MACs' desire to settle cost reports in a timely manner (for example, whether it makes sense to review data 2 years after cost report submission, near the end of the 3 years mentioned in the reopening regulations, or at some other time).

We also are considering allowing hospitals, for a one-time option, to resubmit a cost report with updated Medicaid eligibility information, somewhat similar to our existing DSH policy allowing hospitals a one-time option to have their SSI ratios calculated based on their cost reporting period rather than the Federal fiscal year under 42 CFR 412.106(a)(3). Under this option, we would undertake rulemaking to determine the timeframe for exercising the option (which may be a maximum allowable time after the close of a cost reporting period or a specific window during which the request could be made). We are interested in feedback and comments concerning the viability of these options, as well as any alternative approaches, that could help reduce the number of DSH-related appeals and inform our future rulemaking efforts.

G. Hospital Readmissions Reduction Program: Proposed Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, establishes the Hospital Readmissions Reduction Program. Under the Hospital Readmissions Reduction Program, Medicare payments under the acute inpatient prospective payment system for discharges from an applicable hospital, as defined under section 1886(d) of the Act, may be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a detailed discussion of and additional information on the statutory history of the Hospital Readmissions Reduction Program.

2. Regulatory Background

We refer readers to the following final rules for detailed discussions of the regulatory background and descriptions of the current policies for the Hospital Readmissions Reduction Program:

- FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676);
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401);
- FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676);
- FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048);
- FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543);
- FY 2017 IPPS/LTCH PPS final rule (81 FR 56973 through 56979);
- FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240); and
- FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439).

These rules describe the general framework for the implementation of the Hospital Readmissions Reduction Program, including: (1) The selection of measures for the applicable conditions/procedures; (2) the calculation of the excess readmission ratio (ERR), which is used, in part, to calculate the payment adjustment factor; (3) beginning in FY 2019, the calculation of the proportion of ''dually eligible'' Medicare beneficiaries which is used to stratify hospitals into peer groups and establish the peer group median ERRs; (4) the calculation of the payment adjustment factor, specifically addressing the base operating DRG payment amount, aggregate payments for excess readmissions (including calculating the peer group median ERRs), aggregate payments for all discharges, and the neutrality modifier; (5) the opportunity for hospitals to review and submit corrections using a process similar to what is currently used for posting results on *Hospital Compare;* (6) the adoption of an extraordinary circumstances exception policy to address hospitals that experience a disaster or other extraordinary circumstance; (7) the clarification that the public reporting of ERRs will be posted on an annual basis to the *Hospital Compare* website as soon as is feasible following the review and corrections period; and (8) the specification that the definition of ''applicable hospital'' does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, IPFs, CAHs, and hospitals in United States territories and Puerto Rico.

We also have codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154, which we are proposing to update in this proposed rule to reflect both proposed and previously finalized policies.

The Hospital Readmissions Reduction Program strives to put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians, using information from data-driven insights that are increasingly aligned with meaningful quality measures. We believe the Hospital Readmissions Reduction Program incentivizes hospitals to improve health care quality and value, while giving patients the tools and information needed to make the best decisions for them. To that end, we are committed to monitoring the efficacy of the program to ensure that the Hospital Readmissions Reduction Program improves the lives of patients and reduces cost.

3. Summary of Proposed Policies for the Hospital Readmissions Reduction Program

In this proposed rule, we are proposing the following policies: (1) A measure removal policy that aligns with the removal factor policies previously adopted in other quality reporting and quality payment programs; (2) an update to the program's definition of ''dual-eligible'' beginning with the FY 2021 program year, to allow for a 1-month lookback period in data sourced from the State Medicare Modernization Act (MMA) files to determine dual-eligible status for beneficiaries who die in the month of discharge; (3) a subregulatory process to address any potential future nonsubstantive changes to the payment adjustment factor components; and (4) an update to the regulations at 42 CFR 412.152 and 412.154 to reflect proposed policies and to codify additional previously finalized policies.

We discuss these proposals in greater detail below.

4. Current Measures and Proposed Measure Policies for FY 2020 and Subsequent Years

a. Current Measures

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: Acute myocardial infarction (AMI); heart failure (HF); pneumonia; elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG) surgery. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439) for more information about how the Hospital Readmissions Reduction Program supports CMS' goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Initiative. We continue to believe the measures we have adopted adequately meet the goals of the Hospital Readmissions Reduction Program. Therefore, we are not proposing to remove or adopt any additional measures at this time.

b. Proposed Measure Removal Factors Policy

While we are not proposing to remove any measures from the Hospital Readmissions Reduction Program in this proposed rule, we are proposing to adopt a measure removal factors policy as part of our efforts to ensure that the Hospital Readmissions Reduction Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall burden and costs associated with the program. The adoption of measure removal factors would align the Hospital Readmissions Reduction Program with our other quality reporting and quality payment programs and help ensure consistency in our measure evaluation methodology across programs.

In the FY 2019 IPPS/LTCH PPS final rule, we updated a number of CMS programs' considerations for removing measures from the respective programs. Specifically, we finalized eight measure removal factors for the Hospital IQR Program (83 FR 41540 through 41544), the Hospital VBP Program (83 FR 41441 through 41446), the PCHQR Program (83 FR 41609 through 41611), and the LTCH QRP (83 FR 41625 through 41627).

We believe these removal factors are also appropriate for the Hospital Readmissions Reduction Program, and we believe that alignment between CMS quality programs is important to provide stakeholders with a clear, consistent, and transparent process. Therefore, to align with our other quality reporting and quality payment programs, we are proposing to adopt the following removal factors for the Hospital Readmissions Reduction Program:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures);
- Factor 2. Measure does not align with current clinical guidelines or practice;
- Factor 3. Measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 4. Measure performance or improvement does not result in better patient outcomes;
- Factor 5. Measure can be replaced by a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6. Measure collection or public reporting leads to negative unintended consequences other than patient harm; [395]
- Factor 7. Measure is not feasible to implement as specified; and
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.[396]

We note that these factors are considerations taken into account when deciding whether or not to remove measures, not firm requirements, and that we will propose to remove measures based on these factors on a case-by-case basis. We continue to believe that there may be circumstances in which a measure that meets one or more factors for removal should be retained regardless, because the benefits of a measure can outweigh its drawbacks. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

5. Proposed Updated Definition of ''Dual-Eligible'' Beginning in FY 2021

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38229), as part of implementing the 21st Century Cures Act, we finalized the definition of dual-eligible as follows: ''Dual-eligible is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in the State Medicare Modernization Act (MMA) files for the month the beneficiary was discharged from the hospital.'' In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41437 through 41438), we finalized our proposal to codify this definition at 42 CFR 412.152 along with other definitions pertinent to dual-eligibility calculations for assigning hospitals into peer groups.

In this proposed rule, we are proposing to update our previously finalized definition of ''dual-eligible'' to specify that, for the payment adjustment factors beginning with the FY 2021 program year, ''dual-eligible'' is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in data sourced from the State MMA files for the month the beneficiary was discharged from the hospital, except for those patient beneficiaries

[395] When there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns, CMS will take immediate action to remove a measure from the program and not wait for the annual rulemaking cycle. In such situations, we would promptly retire such measures followed by subsequent confirmation of the retirement in the next IPPS rulemaking. When we do so, we will notify hospitals and the public through the usual hospital and QIO communication channels used for the Hospital Readmissions Reduction Program, which include memo and email notification and QualityNet website articles and postings.

[396] We refer readers to the Hospital IQR Program's measure removal factors discussions in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for additional details on the removal factors and the rationale supporting them.

who die in the month of discharge, who will be identified using the previous month's data sourced from the State MMA files.[397]

The updated definition is necessary to account for misidentification of the dual-eligible status of patient beneficiaries who die in the month of discharge, which can occur under the current definition. We were not aware at the time we finalized our current definition of ''dual-eligible'' that there are times when the data sourced from the State MMA files may underreport the number of beneficiaries with dual-eligibility status for the month in which the beneficiaries dies, and, therefore, these data are not fully accurate reflections of dual-eligible status for the month in which a beneficiary dies. We have identified two situations that lead to the underreporting of dual-eligible patients: (1) The dual-eligible status is not recorded in the month of death; and (2) the dual-eligible status changes from dual in the months prior to death to non-dual in the month of death. While the number of misidentified patient beneficiaries is very small and did not have a substantive impact, we believe that using the most accurate information available is the most appropriate policy for the program and consistent with our initial rationale for using the State MMA files as the source to identify dual-eligibles. When we adopted the current definition of ''dual-eligible'' in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226), we stated, and many commenters agreed, that the State MMA file is considered the most current and most accurate source of data for identifying dual-eligible beneficiaries because the data are also used for operational purposes related to the administration of Medicare Part D benefits.

Our intent was and remains to use the most accurate data available to determine ''dual-eligible'' status in the hospital grouping portion of the payment adjustment. Through our analysis, we believe using a 1-month lookback period within the data sourced from the State MMA files to determine dual-eligible status for beneficiaries who die in the month of discharge will improve the accuracy of the number of beneficiaries identified as having dual-eligible status. We note that we are proposing to update this definition for FY 2021 instead of FY 2020 because of the time associated with updates to the data systems is inconsistent with our ability to finalize this proposal in time for FY 2020 and the lack of a subregulatory policy, which would allow us to make nonsubstantive changes outside of the rulemaking schedule.

We are proposing to revise the definition of ''dual-eligible'' codified at 42 CFR 412.152 to incorporate this update.

6. Proposed Adoption of a Subregulatory Process for Changes to Payment Adjustment Factor Components

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41434), we reiterated our policy regarding the maintenance of technical specifications for quality measures. In adopting our policy for the maintenance of technical specifications in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50039), we stated that it is important to have in place a subregulatory process to incorporate nonsubstantive updates required by the National Quality Forum into the measure specifications we have adopted for the Hospital Readmissions Reduction Program, so that these measures remain up to date. We also stated that we would continue to use notice-and-comment rulemaking for any substantive changes to measure specification. We continue to believe this process is the most expeditious manner possible to ensure that quality measures remain fully up to date while preserving the public's ability to comment on updates that so fundamentally change a measure that it is no longer the same measure that we originally adopted. When we adopted this policy, we received commenter support for our policy of handling substantive and nonsubstantive changes to measures. The policy allows CMS two mechanisms to address measure updates: (1) The use of future proposed rules and public comment periods for substantive changes; and (2) subregulatory processes for nonsubstantive changes which also preserve CMS' autonomy and flexibility, in order to rapidly implement nonsubstantive updates to measures (79 FR 50039).

We now believe it is important for the Hospital Readmissions Reduction Program to adopt an analogous subregulatory process for changes to the payment adjustment factor components to provide similar flexibility to rapidly implement nonsubstantive updates to implement data sourcing and other minor changes when payment adjustment factor components are impacted. We are proposing to adopt a policy under which we would use a subregulatory process to make nonsubstantive changes to the payment adjustment factor components used for the Hospital Readmissions Reduction Program. We previously adopted our payment adjustment factor components policies through the notice-and-comment rulemaking process. The Hospital Readmissions Reduction Program relies on these payment adjustment factor components, including, but not limited to, dual proportion, peer group assignment, peer group median ERR, neutrality modifier, and ratio of DRG payments to total payments, to determine hospital payments in each fiscal year. Each year, we provide details on most of that information in the Hospital Specific Report (HSR) User Guide located on QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412669.* However, there are times when data sourcing and other technical aspects of the payment adjustment factor components change and require updating, even when those changes do not alter the intent of our previously finalized policies. Because the updates to data sourcing and technical aspects of the components are not always linked to the timing of regulatory actions, we believe this proposed policy is prudent to allow for the use of the most up-to-date, accurate information. We reiterate that we would continue to consider all changes to the framework of the components themselves as substantive changes that we would propose through the notice-and-comment rulemaking process.

Most recently, as discussed earlier, we identified an issue with data accuracy for determining dual-eligible status from data sourced from the State MMA files for beneficiaries who die in the same month as discharge. In this proposed rule, we are proposing to amend the definition of ''dual-eligible'' to account for this data issue. However, we would like to clarify that the proposal is not altering the intent of our previously finalized policy. Instead, the proposed updated definition of ''dual-eligible'' allows for the use of the month preceding discharge for identifying dual-eligibles who died during the discharge month after learning that the current files misidentified the dual-eligibility status of certain patient beneficiaries who die in the month of discharge. Although we have identified this issue, and do not believe that it is a substantive change to our policy for determining dual-eligibles, we believe

[397] In addition, it has come to our attention that the determination of dual eligibility is made from data sourced from the State MMA files, not the original State MMA files. The program also considers this to be a nonsubstantive change as the data are obtained from the specified source.

that we should utilize the notice-and-comment rulemaking process to address this clarification because we do not currently have a subregulatory policy in place to address this type of data issue. However, we believe that a subregulatory process for addressing nonsubstantive data issues like the dual-eligible update could be used for similar situations in the future. We would publish these nonsubstantive data changes in the HSR User Guide annually. We note that we would continue to use notice-and-comment rulemaking for substantive changes.

With respect to what constitutes substantive changes versus nonsubstantive changes, we expect to make this determination on a case-by-case basis. In other quality reporting and quality payment programs (77 FR 53504), we stated that substantive changes are those that are so significant that the measures could no longer be considered the same measure. For this proposed policy, we would utilize the same principle; we would deem a change to be substantive and to require notice-and-comment rulemaking when the impact of the change to the payment adjustment factor component was so significant that it could no longer be considered to be the same as the previously finalized component. Examples of nonsubstantive changes would include, but not be limited to, updated naming or locations of data files and/or other minor discrepancies that do not change the intent of the policy. Examples of substantive changes to data might include use of different methodologies to use data than finalized for the payment adjustment factor component or the use of a different component in the methodology for payment calculations.

7. Proposed Applicable Period for FY 2022

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53675) for discussion of our previously finalized policy for defining applicable periods. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41434 through 41435), we finalized the following ''applicable periods'' to calculate the readmission payment adjustment factor for FY 2019, FY 2020, and FY 2021, respectively:

- The 3-year time period of July 1, 2014 through June 30, 2017 for FY 2019;
- The 3-year time period of July 1, 2015 through June 30, 2018 for FY 2020; and
- The 3-year time period of July 1, 2016 through June 30, 2019 for FY 2021.

These are the 3-year periods from which data are being collected in order to calculate ERRs and payment adjustment factors for the fiscal year; this includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment. The ''applicable period'' for dual-eligibles is the same as the ''applicable period'' that we otherwise adopt for purposes of the Hospital Readmissions Reduction Program.

We are proposing, for FY 2022, consistent with the definition specified at § 412.152, that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2017 through June 30, 2020. The applicable period for dual-eligibles for FY 2022 would similarly be the 3-year period from July 1, 2017 through June 30, 2020.

8. Identification of Aggregate Payments for Each Condition/Procedure and All Discharges for FY 2020

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payment amount for an individual hospital for the applicable period for such condition/procedure, using Medicare inpatient claims from the MedPAR file with discharge dates that are within the applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source.

In identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions, we apply the same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions/procedures. For the FY 2020 applicable period, this includes the discharge diagnoses for each applicable condition/procedure based on a list of specific ICD–9–CM or ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition/procedure, because diagnoses and procedure codes for discharges occurring prior to October 1, 2015 were reported under the ICD–9–CM code set, while discharges occurring on or after October 1, 2015 (FY 2016), were reported under the ICD–10–CM and ICD–10–PCS code sets.

We identify Medicare fee-for-service (FFS) claims that meet the criteria described above for each applicable condition/procedure to calculate the aggregate payments for excess readmissions (that is, claims paid for under Medicare Part C (Medicare Advantage) are not included in this calculation). This policy is consistent with the methodology to calculate ERRs based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2020, we are proposing to continue to exclude admissions for patients enrolled in Medicare Advantage, as identified in the Medicare Enrollment Database.

In this proposed rule, for FY 2020, we are proposing to determine aggregate payments for excess readmissions, aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2015, and not later than June 30, 2018. As we stated in FY 2018 IPPS/LTCH PPS final rule (82 FR 38232), we will determine the neutrality modifier using the most recently available full year of MedPAR data. However, we note that, for the purpose of modeling the proposed FY 2020 readmissions payment adjustment factors for this proposed rule, we are using the proportion of dual-eligibles, excess readmission ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2019 Hospital Readmissions Reduction Program applicable period. For the FY 2020 program year, applicable hospitals will have the opportunity to review and correct calculations based on the proposed FY 2020 applicable period of July 1, 2015 to June 30, 2018, before they are made public under our policy regarding reporting of hospital-specific information. Again, we reiterate that this period is intended to review the program calculations, and not the underlying data. For more information on the review and corrections process, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53401).

In this proposed rule, for FY 2020, we are proposing to use MedPAR data from July 1, 2015 through June 30, 2018 for the FY 2020 Hospital Readmissions Reduction Program calculations. Specifically—

- The March 2016 update of the FY 2015 MedPAR file to identify claims within FY 2015 with discharges dates that are on or after July 1, 2015;
- The March 2017 update of the FY 2016 MedPAR file to identify claims within FY 2016;
- The March 2018 update of the FY 2017 MedPAR file to identify claims within FY 2017; and
- The March 2019 update of the FY 2018 MedPAR file to identify claims

within FY 2018 with discharge dates that are on or before June 30, 2018.

9. Calculation of Payment Adjustment Factors for FY 2020

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226), section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within peer groups in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019.

To implement this provision, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237), we finalized several changes to the payment adjustment methodology for FY 2019. First, we finalized that an individual would be counted as a full-benefit dual-eligible patient if the beneficiary was identified as full-benefit dual status in the State Medicare Modernization Act (MMA) files for the month he or she was discharged from the hospital (82 FR 38226 through 38228). Second, we finalized our policy to define the proportion of full benefit dual-eligible beneficiaries as the proportion of dual-eligible patients among all Medicare FFS and Medicare Advantage stays (82 FR 38226 through 38228). Third, we finalized our policy to define the data period for determining dual-eligibility as the 3-year data period corresponding to the Program's applicable period (82 FR 38229). Fourth, we finalized our policy to stratify hospitals into quintiles, or five peer groups, based on their proportion of dual-eligible patients (82 FR 38229 through 38231). Finally, we finalized our policy to use the median ERR for the hospital's peer group in place of 1.0 in the payment adjustment formula and apply a uniform modifier to maintain budget neutrality (82 FR 38231 through 38237). The payment adjustment formula would then be:

$$P = 1 - \min\{.03, \sum_{dx} \frac{NM * Payment(dx) * \max\{(\text{ERR(dx)} - \text{Median peer group ERR(dx)}),0\})}{All\ payments}\}$$

where dx is AMI, HF, pneumonia, COPD, THA/TKA or CABG and payments refers to the base operating DRG payments. The payment reduction (1–P) resulting from use of the median ERR for the peer group is scaled by a neutrality modifier to achieve budget neutrality. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237) for a detailed discussion of the payment adjustment methodology. We are not proposing any changes to this payment adjustment calculation methodology for FY 2020.

10. Calculation of Payment Adjustment for FY 2020

Section 1886(q)(3)(A) of the Act defines the payment adjustment factor for an applicable hospital for a fiscal year as ''equal to the greater of: (i) The ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C).'' Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions, and (ii) the aggregate payments for all discharges, scaled by the neutrality modifier. The calculation of this ratio is codified at § 412.154(c)(1) of the regulations and the floor adjustment factor is codified at § 412.154(c)(2) of the regulations. Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, codified in our regulations at § 412.154(c)(2), for FY 2020, the payment adjustment factor will be either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2020, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

For additional information on the FY 2020 payment calculation, we refer readers to the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid= 1228776124112.*

11. Confidential Reporting of Stratified Data for Hospital Quality Measures

Beginning as early as the spring of 2020, CMS plans to include in confidential hospital-specific reports (HSR) data stratified by patient dual eligible status for the six readmissions measures included in the Hospital Readmissions Reduction Program. These data will include two disparity methodologies designed to illuminate potential disparities within individual hospitals and across hospitals nationally and will supplement the measure data currently publicly reported on the *Hospital Compare* website. The first methodology, the Within-Hospital Disparity Method highlights differences in outcomes for dual eligible versus non-dual eligible patients within an individual hospital, while the second methodology, the Dual Eligible Outcome Method, allows for a comparison of performance in care for dual-eligible patients across hospitals (82 FR 38405 through 38407; 83 FR 41598). These two disparity methods are separate from the stratified methodology used by the Hospital Readmissions Reduction Program, and we emphasize that the two disparity methods would not be used in payment adjustment factors calculations under the Hospital Readmissions Reduction Program. We believe that providing the results of both disparity methods alongside a hospital's measure data as a point of reference allows for a more meaningful comparison and comprehensive assessment of the quality of care for patients with social risk factors and the identification of providers where disparities in health care may exist. We also believe the two disparity methods provide additional perspectives on health care equity (83 FR 41598).

We believe hospitals can use their results from the disparity methods to identify and develop strategies to reduce disparities in the quality of care for patients through targeted improvement efforts (83 FR 41598). The two disparity methods and the stratified methodology used by the Hospital Readmissions Reduction Program are part of CMS' broader effort to account for social risk factors in quality measurement and quality payment programs. We refer readers to section VIII.A.9. of the preamble of this proposed rule for more information on confidential reporting of stratified data for hospital quality measures. We further refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57167 through 57168), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38324 through 38326; 82 FR 38403 through 38409), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41597 through 41601) for detailed discussions on disparity reporting.

We note that the two disparity methods do not place any additional collection or reporting burden on hospitals because dual-eligibility data are readily available in claims data. In addition, we reiterate that these confidential hospital-specific reports data do not impact the calculation of hospital payment adjustment factors under the Hospital Readmissions Reduction Program.

12. Proposed Revisions of Regulatory Text

We are proposing to revise 42 CFR 412.152 to reflect proposed policies and to codify previously finalized policies. Specifically, we are proposing to revise the definition of ''aggregate payments for excess readmissions'', as discussed earlier, to specify that it means the sum of the product for each applicable condition, among others, of ''the excess readmission ratio for the hospital for the applicable period minus *the peer group median excess readmission ratio*'' (instead of minus 1) (proposed paragraph (3) of the definition) and to include the neutrality modifier—a multiplicative factor that equates total Medicare savings under the current stratified methodology to the previous non-stratified methodology (proposed paragraph (4) of the definition).

We are proposing to revise the definition of ''applicable condition'' to include other conditions and procedures as determined appropriate by the Secretary. In expanding the applicable conditions, the Secretary will seek endorsement of the entity with a contract under section 1890(a) of the Act, but may apply such measures without such an endorsement in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We are proposing to revise the definition of ''base operating DRG payment amount'', with respect to a sole community hospital that receives payments under § 412.92(d) or a Medicare-dependent, small rural hospital that receives payments under § 412.108(c), to remove the applicability date of FY 2013, and to specify that this amount also *includes* the difference between the hospital-specific payment rate and the Federal payment rate determined under the subpart. This proposal is intended to align the regulatory text with section 1886(q)(2)(b)(i) of the Act, because the regulatory text was not updated following the expiration of the FY 2013 changes.

We are proposing to revise the definition of ''dual-eligible'' to specify that, for payment adjustment factors beginning in FY 2021, dual-eligible is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in data sourced from the State MMA files for the month the beneficiary was discharged from the hospital except for those patient beneficiaries who die in the month of discharge, which will be identified using the previous month's data as sourced from the State MMA files, as discussed earlier.

We are proposing to revise § 412.154(e) to specify that the limitations on administrative or judicial review would include the neutrality modifier and the proportion of dual-eligibles as discussed earlier (proposed new paragraphs (e)(4) and (5); existing paragraph (e)(4) would be redesignated as paragraph (e)(6)).

H. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes

1. Background

a. Statutory Background and Overview of Past Program Years

Section 1886(o) of the Act requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year (FY) to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660); the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50676 through 50707); the CY 2014 OPPS/ASC final rule (78 FR 75120 through 75121); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49544 through 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 56979 through 57011); the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38240 through 38269); and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41472).

We also have codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2020 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), and we refer readers to that rule for further details.

Under section 1886(o)(7)(C)(v) of the Act, the applicable percent for the FY 2020 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2020 is approximately $1.9 billion, based on the December 2018 update of the FY 2018 MedPAR file. We intend to update this estimate for the FY 2020 IPPS/LTCH PPS final rule using the March 2019 update of the FY 2018 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We will then calculate a value-based incentive payment adjustment factor that will be applied to the base operating DRG payment amount for each discharge occurring in FY 2020, on a per-claim basis. We are publishing proxy value-based incentive payment adjustment factors in Table 16 associated with this proposed rule (which is available via the internet on the CMS website). The proxy factors are based on the TPSs from the FY 2019 program year. These FY 2019 performance scores are the most recently available performance scores hospitals have been given the opportunity to review and correct. The slope of the linear exchange function used to calculate the proxy value-based incentive payment adjustment factors in

Table 16 is 2.8391388973. This slope, along with the estimated amount available for value-based incentive payments, is also published in Table 16.

We intend to update this table as Table 16A in the final rule (which will be available on the CMS website) to reflect changes based on the March 2019 update to the FY 2018 MedPAR file. We also intend to update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2020 will continue to be based on historic FY 2019 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2020 program year until after the FY 2020 IPPS/LTCH PPS final rule is published.

After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2020, we will post Table 16B (which will be available via the internet on the CMS website) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2020 program year. We expect Table 16B will be posted on the CMS website in the fall of 2019.

2. Retention and Removal of Quality Measures

a. Retention of Previously Adopted Hospital VBP Program Measures and Relationship Between the Hospital IQR and Hospital VBP Program Measure Sets

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41441), we finalized a revision to our regulations at 42 CFR 412.164(a) to clarify that once we have complied with the statutory prerequisites for adopting a measure for the Hospital VBP Program (that is, we have selected the measure from the Hospital IQR Program measure set and included data on that measure on *Hospital Compare* for at least one year prior to its inclusion in a Hospital VBP Program performance period), the Hospital VBP Program statute does not require that the measure continue to remain in the Hospital IQR Program. We are not proposing any changes to these policies in this proposed rule.

b. Measure Removal Factors for the Hospital VBP Program

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41441 through 41446), in alignment with the Hospital IQR Program, we finalized the following measure removal factors for the Hospital VBP Program:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures), defined as: Statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤0.10; [398]
- Factor 2. A measure does not align with current clinical guidelines or practice;
- Factor 3. The availability of a more broadly applicable measure (across settings or populations), or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 4. Performance or improvement on a measure does not result in better patient outcomes;
- Factor 5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm;
- Factor 7. It is not feasible to implement the measure specifications; and
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

We noted that these removal factors will be considerations taken into account when deciding whether or not to remove measures, not firm requirements. We continue to believe that there may be circumstances in which a measure that meets one or more factors for removal should be retained regardless, because the drawbacks of removing a measure could be outweighed by other benefits to retaining the measure. In addition, to further align with policies adopted in the Hospital IQR Program (74 FR 43864), in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41446), we finalized a policy that if we believe continued use of a measure poses specific patient safety concerns, we may promptly remove the measure from the program without rulemaking and notify hospitals and the public of the removal of the measure along with the reasons for its removal through routine communication channels and then confirm the removal of the measure from the Hospital VBP Program measure set in rulemaking. We are not proposing any changes to these policies in this proposed rule.

c. Summary of Previously Adopted Measures for the FY 2022 and FY 2023 Program Years

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41454 through 41456) and below for tables showing summaries of previously adopted measures for the FY 2022 and FY 2023 program years. We note that we are not proposing to add new measures to or remove measures from the Hospital VBP Program in this proposed rule.

SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2022 PROGRAM YEAR

Measure short name	Domain/measure name	NQF No.
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
	Safety Domain	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139

[398] We previously adopted the two criteria for determining the ''topped-out'' status of Hospital VBP Program measures in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50055).

SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2022 PROGRAM YEAR—Continued

Measure short name	Domain/measure name	NQF No.
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure.	1717
Clinical Outcomes Domain		
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
COMP–HIP–KNEE *	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158

* We note that we are updating the short name of the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure (NQF #1550) from THA/TKA to COMP–HIP–KNEE in order to maintain consistency with the updated Measure ID and short name used in tables on the *Hospital Compare* website and hospital reports for the Hospital VBP Program. This updated name is used throughout section IV.H. of the preamble of this proposed rule.

SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2023 PROGRAM YEAR

Measure short name	Domain/measure name	NQF No.
Person and Community Engagement Domain		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure.	1717
CMS PSI 90 *	CMS Patient Safety and Adverse Events Composite *	0531
Clinical Outcomes Domain		
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
COMP–HIP–KNEE	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550

SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2023 PROGRAM YEAR—Continued

Measure short name	Domain/measure name	NQF No.
	Efficiency and Cost Reduction Domain	
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158

*We note that we have updated the name of the Patient Safety and Adverse Events Composite (PSI 90) to the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) when it is used in CMS programs due to transition of the measure from AHRQ to CMS.

3. Previously Adopted Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998 through 57003) for baseline and performance periods that we have adopted for the FY 2019, FY 2020, FY 2021, and FY 2022 program years. In the same final rule, we finalized a schedule for all future baseline and performance periods for previously adopted measures. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256 through 38261) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41466 through 41469) for additional baseline and performance periods that we have adopted for the FY 2022, FY 2023, and subsequent program years.

b. Person and Community Engagement Domain

Since the FY 2015 program year, we have adopted a 12-month baseline period and a 12-month performance period for measures in the Person and Community Engagement domain (previously referred to as the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain) (77 FR 53598; 78 FR 50692; 79 FR 50072; 80 FR 49561). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998), we finalized our proposal to adopt a 12-month performance period for the Person and Community Engagement domain that runs on the calendar year 2 years prior to the applicable program year and a 12-month baseline period that runs on the calendar year 4 years prior to the applicable program year, for the FY 2019 program year and subsequent years.

We are not proposing any changes to these policies in this proposed rule.

c. Clinical Outcomes Domain

For the FY 2020 and FY 2021 program years, we adopted a 36-month baseline period and a 36-month performance period for measures in the Clinical Outcomes domain (previously referred to as the Clinical Care domain) (79 FR 50073; 80 FR 49563 through 49564). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57001), we also adopted a 22-month performance period and a 36-month baseline period specifically for the MORT–30–PN (updated cohort) measure for the FY 2021 program year.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we adopted a 36-month performance period and a 36-month baseline period for the FY 2022 program year for each of the previously finalized measures in the Clinical Outcomes domain—that is, the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, COMP–HIP–KNEE, and MORT–30–CABG measures. In the same final rule, we adopted a 34-month performance period and a 36-month baseline period for the MORT–30–PN (updated cohort) measure for the FY 2022 program year.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38259), we adopted a 36-month performance period and a 36-month baseline period for the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, MORT–30–PN (updated cohort), and COMP–HIP–KNEE measures for the FY 2023 program year and subsequent years. Specifically, for the mortality measures (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, and MORT–30–PN (updated cohort)), the performance period runs for 36 months from July 1, five years prior to the applicable fiscal program year, to June 30, two years prior to the applicable fiscal program year, and the baseline period runs for 36 months from July 1, ten years prior to the applicable fiscal program year, to June 30, seven years prior to the applicable fiscal program year. For the COMP–HIP–KNEE measure, the performance period runs for 36 months from April 1, five years prior to the applicable fiscal program year, to March 31, two years prior to the applicable fiscal program year, and the baseline period runs for 36 months from April 1, ten years prior to the applicable fiscal program year, to March 31, seven years prior to the applicable fiscal program year.

We are not proposing any changes to the length of these performance or baseline periods in this proposed rule.

d. Safety Domain

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we finalized our proposal to adopt a performance period for all measures in the Safety domain—with the exception of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure—that runs on the calendar year 2 years prior to the applicable program year and a baseline period that runs on the calendar year 4 years prior to the applicable program year for the FY 2019 program year and subsequent program years.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38258), for the FY 2023 program year, we adopted a 21-month baseline period (October 1, 2015 to June 30, 2017) and a 24-month performance period (July 1, 2019 to June 30, 2021) for the CMS PSI 90 measure. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38258 through 38259), we adopted a 24-month performance period and a 24-month baseline period for the CMS PSI 90 measure for the FY 2024 program year and subsequent years. Specifically, the performance period runs from July 1, four years prior to the applicable fiscal program year, to June 30, two years prior to the applicable fiscal program year, and the baseline period runs from July 1, eight years prior to the applicable fiscal program year, to June 30, six years prior to the applicable fiscal program year.

We are not proposing any changes to these policies in this proposed rule.

e. Efficiency and Cost Reduction Domain

Since the FY 2016 program year, we have adopted a 12-month baseline period and a 12-month performance period for the MSPB measure in the Efficiency and Cost Reduction domain (78 FR 50692; 79 FR 50072; 80 FR 49562). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998), we finalized our proposal to adopt a 12-month performance period for the MSPB measure that runs on the calendar year 2 years prior to the applicable program year and a 12-month baseline period

that runs on the calendar year 4 years prior to the applicable program year for the FY 2019 program year and subsequent years.

We are not proposing any changes to these policies in this proposed rule.

f. Summary of Previously Adopted Baseline and Performance Periods for the FY 2022 Through FY 2025 Program Years

The tables below summarize the baseline and performance periods that we have previously adopted.

Previously Adopted Baseline and Performance Periods for the FY 2022 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2018 – December 31, 2018	● January 1, 2020 – December 31, 2020
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG) ● MORT-30-PN (updated cohort) ● COMP-HIP-KNEE	● July 1, 2012 – June 30, 2015 ● July 1, 2012 – June 30, 2015 ● April 1, 2012 – March 31, 2015	● July 1, 2017 – June 30, 2020 ● September 1, 2017 – June 30, 2020 ● April 1, 2017 – March 31, 2020
Safety ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	● January 1, 2018 – December 31, 2018	● January 1, 2020 – December 31, 2020
Efficiency and Cost Reduction ● MSPB	● January 1, 2018 – December 31, 2018	● January 1, 2020 – December 31, 2020

Previously Adopted Baseline and Performance Periods for the FY 2023 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2019 – December 31, 2019	● January 1, 2021 – December 31, 2021
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort) ● COMP-HIP-KNEE	● July 1, 2013 – June 30, 2016 ● April 1, 2013 – March 31, 2016	● July 1, 2018 – June 30, 2021 ● April 1, 2018 – March 31, 2021

Previously Adopted Baseline and Performance Periods for the FY 2023 Program Year		
Domain	**Baseline Period**	**Performance Period**
Safety ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) ● CMS PSI 90	● January 1, 2019 – December 31, 2019 ● October 1, 2015 – June 30, 2017	● January 1, 2021 – December 31, 2021 ● July 1, 2019 – June 30, 2021
Efficiency and Cost Reduction ● MSPB	● January 1, 2019 – December 31, 2019	● January 1, 2021 – December 31, 2021

Previously Adopted Baseline and Performance Periods for the FY 2024 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2020 – December 31, 2020	● January 1, 2022 – December 31, 2022
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort) ● COMP-HIP-KNEE	● July 1, 2014 – June 30, 2017 ● April 1, 2014 – March 31, 2017	● July 1, 2019 – June 30, 2022 ● April 1, 2019 – March 31, 2022
Safety ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) ● CMS PSI 90	● January 1, 2020 – December 31, 2020 ● July 1, 2016 – June 30, 2018	● January 1, 2022 – December 31, 2022 ● July 1, 2020 – June 30, 2022
Efficiency and Cost Reduction ● MSPB	● January 1, 2020 – December 31, 2020	● January 1, 2022 – December 31, 2022

Previously Adopted Baseline and Performance Periods for the FY 2025 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2021 – December 31, 2021	● January 1, 2023 – December 31, 2023
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort) ● COMP-HIP-KNEE	● July 1, 2015 – June 30, 2018 ● April 1, 2015 – March 31, 2018	● July 1, 2020 – June 30, 2023 ● April 1, 2020 – March 31, 2023
Safety ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) ● CMS PSI 90	● January 1, 2021 – December 31, 2021 ● July 1, 2017 – June 30, 2019	● January 1, 2023 – December 31, 2023 ● July 1, 2021 – June 30, 2023
Efficiency and Cost Reduction ● MSPB	● January 1, 2021 – December 31, 2021	● January 1, 2023 – December 31, 2023

4. Performance Standards for the Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established no later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program.

In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53599 through 53605; 78 FR 50694 through 50699; and 79 FR 50077 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41469 through 41470) for previously established performance standards for the FY 2021 program year.

We note that the performance standards for the following measures are calculated with lower values representing better performance:

- CDC NHSN HAI measures (CLABSI, CAUTI, CDI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI);
- CMS PSI 90 measure;
- COMP–HIP–KNEE measure; and
- MSPB measure.

This distinction is made in contrast to other measures—HCAHPS and the mortality measures, which use survival rates rather than mortality rates—for which higher values indicate better performance. As discussed further in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50684), the performance standards for the Colon and Abdominal Hysterectomy SSI measure are computed separately for each procedure stratum, and we first award achievement and improvement points to each stratum separately, and then compute a weighted average of the points awarded to each stratum by predicted infections.

b. Previously Established and Estimated Performance Standards for the FY 2022 Program Year

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57009), we established performance standards for the FY 2022

program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time.

In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) and codified at 42 CFR 412.160, we are estimating additional performance standards for the FY 2022 program year. We note that the numerical values for the performance standards for the Safety and Person and Community Engagement domains for the FY 2022 program year in the tables below are estimates based on the most recently available data, and we intend to update the numerical values in the FY 2020 IPPS/LTCH PPS final rule.

The previously established and estimated performance standards for the measures in the FY 2022 program year are set out in the tables below.

Previously Established and Estimated Performance Standards for the FY 2022 Program Year: Safety, Clinical Outcomes, and Efficiency and Cost Reduction Domains

Measure Short Name	Achievement Threshold	Benchmark
Safety Domain♦		
CAUTI*	0.740	0.000
CLABSI*	0.667	0.000
CDI*	0.668	0.045
MRSA Bacteremia*	0.768	0.000
Colon and Abdominal Hysterectomy SSI*	• 0.742 • 0.745	• 0.000 • 0.000
Clinical Outcomes Domain		
MORT-30-AMI#	0.861793	0.881305
MORT-30-HF#	0.879869	0.903608
MORT-30-PN (updated cohort)#	0.836122	0.870506
MORT-30-COPD#	0.920058	0.936962
MORT-30-CABG#†	0.968210	0.979000
COMP-HIP-KNEE*#	0.029833	0.021493
Efficiency and Cost Reduction Domain		
MSPB*#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

♦ The estimated performance standards displayed in this table for the Safety domain measures were calculated using one quarter (Q4) CY 2017 data and three quarters (Q1, Q2, and Q3) CY 2018 data. We will update this table's performance standards using four quarters of CY 2018 data in the final rule.

* Lower values represent better performance.

Previously established performance standards.

† After publication of the FY 2017 IPPS/LTCH PPS final rule, we determined there was a display error in the performance standards for this measure. Specifically, the Achievement Threshold and Benchmark values, while accurate, were presented in the wrong categories. We corrected this issue in the FY 2018 IPPS/LTCH PPS final rule, and the correct performance standards are displayed in the table above.

The eight dimensions of the HCAHPS measure are calculated to generate the HCAHPS Base Score. For each of the eight dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is then summed across the eight dimensions to create the HCAHPS Base Score (0–80 points). Each of the eight dimensions is of equal weight; therefore, the HCAHPS Base Score ranges from 0 to 80 points. HCAHPS Consistency Points are then calculated, which range from 0 to 20 points. The Consistency Points take into consideration the scores of all eight Person and Community Engagement dimensions. The final element of the scoring formula is the summation of the HCAHPS Base Score and the HCAHPS Consistency Points, which results in the Person and Community Engagement Domain score that ranges from 0 to 100 points.

ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2022 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN ±

HCAHPS survey dimension	Floor (minimum)	Achievement threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	10.93	79.06	87.42
Communication with Doctors	13.98	79.69	87.97
Responsiveness of Hospital Staff	16.92	65.97	81.33
Communication about Medicines	8.50	63.60	74.56
Hospital Cleanliness & Quietness	4.39	65.47	79.49
Discharge Information	65.62	87.17	91.96
Care Transition	5.11	51.88	63.18
Overall Rating of Hospital	18.86	71.48	85.32

±The estimated performance standards displayed in this table were calculated using one quarter (Q4) CY 2017 data and three quarters (Q1, Q2, and Q3) CY 2018 data. We will update this table's performance standards using four quarters of CY 2018 data in the FY 2020 IPPS/LTCH PPS final rule.

c. Previously Established Performance Standards for Certain Measures for the FY 2023 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38264 through 38265), we established performance standards for the FY 2023 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and for the Efficiency and Cost Reduction domain measure (MSPB). In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41471 through 41472), we established, for the FY 2023 program year, the performance standards for the Safety domain measure, CMS PSI 90. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for these measures are set out in the table below.

PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2023 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Safety Domain		
CMS PSI 90*	0.972658	0.760882.
Clinical Outcomes Domain		
MORT–30–AMI	0.866548	0.885499.
MORT–30–HF	0.881939	0.906798.
MORT–30–PN (updated cohort)	0.840138	0.871741.
MORT–30–COPD	0.919769	0.936349.
MORT–30–CABG	0.968747	0.979620.
COMP–HIP–KNEE*	0.027428	0.019779.
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period

* Lower values represent better performance.

d. Previously Established and Newly Established Performance Standards for Certain Measures for the FY 2024 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472), we established performance standards for the FY 2024 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time.

In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) and codified at 42 CFR 412.160, we are establishing performance standards for the CMS PSI 90 measure for the FY 2024 program year. The previously established and newly established performance standards for these measures are set out in the table below.

PREVIOUSLY ESTABLISHED AND NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2024 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Safety Domain		
CMS PSI 90 *	0.968841	0.754176
Clinical Outcomes Domain		
MORT–30–AMI #	0.869247	0.887868
MORT–30–HF #	0.882308	0.907733
MORT–30–PN (updated cohort) #	0.840281	0.872976
MORT–30–COPD #	0.916491	0.934002
MORT–30–CABG #	0.969499	0.980319
COMP–HIP–KNEE *#	0.025396	0.018159
Efficiency and Cost Reduction Domain		
MSPB *#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period

* Lower values represent better performance.
# Previously established performance standards.

e. Newly Established Performance Standards for Certain Measures for the FY 2025 Program Year

As discussed above, we have adopted certain measures for the Clinical Outcomes domain (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain (MSPB) for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513), and our performance standards definitions codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2025 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in the table below.

NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2025 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain		
MORT–30–AMI	0.872624	0.889994.
MORT–30–HF	0.883990	0.910344.
MORT–30–PN (updated cohort)	0.841475	0.874425.
MORT–30–COPD	0.915127	0.932236.
MORT–30–CABG	0.970100	0.979775.
COMP–HIP–KNEE **	0.025332	0.017946.

NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2025 PROGRAM YEAR—Continued

Measure short name	Achievement threshold	Benchmark
Efficiency and Cost Reduction Domain		
MSPB*#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

5. Scoring Methodology and Data Requirements

a. Domain Weighting for the FY 2022 Program Year and Subsequent Years for Hospitals That Receive a Score on All Domains

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266), we finalized our proposal to retain the equal weight of 25 percent for each of the four domains in the Hospital VBP Program for the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. In FY 2019 IPPS/LTCH PPS rulemaking (83 FR 20416 through 20420; 41459 through 41464), we proposed, but did not adopt, any changes to the Hospital VBP Program domains and weighting. We are not proposing any changes to these domain weights in this proposed rule.

b. Domain Weighting for the FY 2022 Program Year and Subsequent Years for Hospitals Receiving Scores on Fewer Than Four Domains

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50084 through 50085), for the FY 2017 program year and subsequent years, we adopted a policy that hospitals must receive domain scores on at least three of four quality domains in order to receive a TPS, and hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted. We are not proposing any changes to these domain weights in this proposed rule.

c. Minimum Numbers of Measures for Hospital VBP Program Domains

Based on our previously finalized policies (82 FR 38266), for a hospital to receive domain scores for the FY 2021 program year and subsequent years:

- A hospital must report a minimum number of 100 completed HCAHPS surveys for a hospital to receive a Person and Community Engagement domain score.
- A hospital must receive a minimum of two measure scores within the Clinical Outcomes domain to receive a Clinical Outcomes domain score.
- A hospital must receive a minimum of two measure scores within the Safety domain to receive a Safety domain score.
- A hospital must receive a minimum of one measure score within the Efficiency and Cost Reduction domain to receive an Efficiency and Cost Reduction domain score.

We are not proposing any changes to these policies in this proposed rule.

d. Minimum Numbers of Cases for Hospital VBP Program Measures

(1) Background

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. For additional discussion of the previously finalized minimum numbers of cases for measures under the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531); the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74534); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53610); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266 through 38267); and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41465 through 41466). We are not proposing any changes to these policies in this proposed rule.

(2) Summary of Previously Adopted Minimum Numbers of Cases

The previously adopted minimum numbers of cases for these measures are set forth in the table below.

PREVIOUSLY ADOPTED MINIMUM CASE NUMBER REQUIREMENTS FOR THE FY 2022 PROGRAM YEAR AND SUBSEQUENT YEARS

Measure short name	Minimum number of cases
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed HCAHPS surveys.
Clinical Outcomes Domain	
MORT–30–AMI	Hospitals must report a minimum number of 25 cases.
MORT–30–HF	Hospitals must report a minimum number of 25 cases.
MORT–30–PN (updated cohort)	Hospitals must report a minimum number of 25 cases.
MORT–30–COPD	Hospitals must report a minimum number of 25 cases.
MORT–30–CABG	Hospitals must report a minimum number of 25 cases.
COMP–HIP–KNEE	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.

PREVIOUSLY ADOPTED MINIMUM CASE NUMBER REQUIREMENTS FOR THE FY 2022 PROGRAM YEAR AND SUBSEQUENT YEARS—Continued

Measure short name	Minimum number of cases
Colon and Abdominal Hysterectomy SSI.	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CMS PSI 90	Hospitals must report a minimum of three eligible cases on any one underlying indicator.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

e. Proposed Administrative Policies for NHSN Healthcare-Associated Infection (HAI) Measure Data

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41553), beginning with the CY 2020 reporting period, the Hospital IQR Program finalized removal of the five CDC NHSN HAI measures that are used in both the Hospital VBP and HAC Reduction Programs (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI). Since these measures were adopted in the Hospital VBP Program, the Hospital VBP Program has used the same data to calculate the CDC NHSN HAI measures that is used by the Hospital IQR Program. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41475 through 41478), the HAC Reduction Program adopted data collection policies for the CDC NHSN HAI measures, beginning on January 1, 2020 with CY 2020 submissions, which will use the same process as the Hospital IQR Program for hospitals to report, review, and correct CDC NHSN HAI measure data. Furthermore, the HAC Reduction Program also adopted processes to validate the CDC NHSN HAI measures used in the HAC Reduction Program beginning with Q3 2020 discharges (83 FR 41478 through 41483). These processes are intended to reflect, to the greatest extent possible, the processes previously established for the Hospital IQR Program in order to aid continued hospital reporting through clear and consistent requirements. In section IV.I.7. of the preamble of this proposed rule, the HAC Reduction Program is proposing additional refinements to its validation process for the CDC NHSN HAI measures in the HAC Reduction Program and providing clarifications regarding validation processes.

To streamline and simplify processes across hospital programs, we are proposing that the Hospital VBP Program will use the same data to calculate the CDC NHSN HAI measures that the HAC Reduction Program uses for purposes of calculating the measures under that program, beginning on January 1, 2020 for CY 2020 data collection, which would apply to the Hospital VBP Program starting with data for the FY 2022 program year performance period. This proposed start date aligns with the effective date of the removal of the measures from the Hospital IQR Program and the date when data on those measures will begin to be reported for the HAC Reduction Program, allowing for a seamless transition. We note that the data used by the HAC Reduction Program will be the same data previously used by the Hospital IQR Program, and therefore, we do not anticipate any changes in the use of such data for the Hospital VBP Program.

We also are proposing that the Hospital VBP Program will use the same processes adopted by the HAC Reduction Program for hospitals to review and correct data for the CDC NHSN HAI measures and will rely on HAC Reduction Program validation to ensure the accuracy of CDC NHSN HAI measure data used in the Hospital VBP Program. We note that the processes for hospitals to submit, review, and correct their data for these measures are the same processes previously used by the Hospital IQR Program. We believe that using the HAC Reduction Program review and correction process will satisfy the requirement in section 1886(o)(10)(A)(ii) of the Act to allow hospitals to review and submit corrections for Hospital VBP Program information that will be made public with respect to each hospital. In addition, as noted earlier, the HAC Reduction Program's validation processes are intended to reflect, to the greatest extent possible, the processes previously established for the Hospital IQR Program. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41483) for a discussion of those processes in the HAC Reduction Program.[399] We believe relying on the HAC Reduction Program's validation process would be sufficient for purposes of ensuring the accuracy of CDC NHSN HAI measure data under the Hospital VBP Program. We believe that these policies will ensure that the use of the same data for the Hospital VBP Program will result in accurate measure scores under the Hospital VBP Program.

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41475 through 41484) for additional details on the HAC Reduction Program's data collection, review and correction, validation, and data accuracy policies for the CDC NHSN HAI measures. We also refer readers to sections IV.I.6. and IV.I.7. of the preamble of this proposed rule for additional information about HAC Reduction Program data collection, review and correction, and proposed refinements to validation policies for the CDC NHSN HAI measures.

I. Hospital-Acquired Condition (HAC) Reduction Program

1. Background

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program. For a detailed discussion of the statutory basis of the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50708 through 50709). For a further description of our previously finalized policies for the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS

[399] The FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41483) includes additional information regarding provider selection, targeting criteria, calculation of the confidence, education review process, and application of validation penalty for the HAC Reduction Program's validation processes compared to the Hospital IQR Program's processes. We also refer readers to section IV.I.7. of the preamble of this proposed rule for proposed changes to the validation selection methodology and proposed clarifications to the validation filtering methodology for the HAC Reduction Program.

final rule (78 FR 50707 through 50729), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011 through 57026), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38269 through 38278), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492). These policies describe the general framework for implementation of the HAC Reduction Program, including: (1) The relevant definitions applicable to the program; (2) the payment adjustment under the program; (3) the measure selection process and conditions for the program, including a risk adjustment- and scoring methodology; (4) performance scoring; (5) data collection; (6) validation; (7) the process for making hospital-specific performance information available to the public, including the opportunity for a hospital to review the information and submit corrections; and (8) limitation of administrative and judicial review. We remind readers that data collection and validation (items (5) and (6)) policies were newly finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492).

We also have codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172. In section IV.I.12. of the preamble of this proposed rule, we are proposing to update 42 CFR 412.172(f) to reflect policies finalized in the FY 2019 IPPS/LTCH PPS final rule.

2. Implementation of the HAC Reduction Program for FY 2020

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492), we reviewed the HAC Reduction Program in the context of our Meaningful Measures Initiative. The HAC Reduction Program addresses the priority areas of making care safer by reducing harm caused in the delivery of care. The measures in the Program generally represent ''never events'' [400] and often, if not always, assess the incidence of preventable conditions. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41547 through 41553), for the Hospital IQR Program, as part of the Meaningful Measures Initiative, we deduplicated the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) beginning with the Hospital IQR Program's FY 2020 payment determination, and the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) measures (CDC NHSN HAI measures) from the Hospital IQR Program beginning in CY 2020/FY 2022 payment determination. However, we retained these measures in the HAC Reduction Program because we believe these measures will continue to encourage hospitals to address the serious harm caused by these adverse events while still using the most parsimonious measure set available. To that end, however, we were required to adopt numerous HAC Reduction Program-specific CDC NHSN HAI measure policies, including data collection, validation requirements, and scoring associated with data completeness, timeliness, and accuracy, to transition the administrative processes on which the HAC Reduction Program had historically relied on the Hospital IQR Program to support. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41475 through 41484), for the HAC Reduction Program, we formally adopted analogous processes to independently manage these administrative processes to receive CDC NHSN data beginning in CY 2020 and with validation beginning with Q3 CY 2020 infectious events.

In this proposed rule, we are proposing to clarify policies that we finalized for the HAC Reduction Program in the FY 2019 IPPS/LTCH PPS final rule, so that they are implemented as intended. We are specifically proposing to: (1) Adopt a measure removal policy that aligns with the removal factor policies previously adopted in other quality reporting and quality payment programs; (2) clarify administrative policies for validation of the CDC NHSN HAI measures; (3) adopt the data collection periods for the FY 2022 program year; and (4) update regulations for the HAC Reduction Program at 42 CFR 412.172(f) to reflect policies finalized in the FY 2019 IPPS/LTCH PPS final rule.

3. Current Measures for FY 2020 and Subsequent Years

The HAC Reduction Program has adopted six measures. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the use of five CDC NHSN HAI measures: (1) CAUTI; (2) CDI; (3) CLABSI; (4) Colon and Abdominal Hysterectomy SSI; and (5) MRSA Bacteremia. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57014), we finalized the use of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure. These previously finalized measures, with their full measure names, are shown in the table below.[401]

HAC Reduction Program Measures for FY 2019

Short name	Measure name	NQF #
CMS PSI 90	CMS Patient Safety Indicator (PSI) 90	0531
CAUTI	CDC NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716

[400] The term ''Never Event'' was first introduced in 2001 by Ken Kizer, MD, former CEO of the National Quality Forum (NQF), in reference to particularly shocking medical errors (such as wrong-site surgery) that should never occur. Over time, the list has been expanded to signify adverse events that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and usually preventable. The NQF initially defined 27 such events in 2002. The list has been revised since then, most recently in 2011, and now consists of 29 events grouped into 7 categories: Surgical, product or device, patient protection, care management, environmental, radiologic, and criminal.'' Never Events are available at: *https://psnet.ahrq.gov/primers/primer/3/neverevents*.

[401] In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41485 through 41489), we finalized the equal weighting of measures to coincide with the removal of Domains for scoring purposes, so these measures are no longer grouped by Domain.

In this proposed rule, we are not proposing to add or remove any measures.

4. Measures Specification and Technical Specifications

As we stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100 through 50101) and reiterated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41475), we will use a subregulatory process to make nonsubstantive updates to measures used for the HAC Reduction Program and use notice-and-comment rulemaking to adopt substantive updates to measures. We are not making any substantive changes to the measures this year. Technical specifications for the CMS PSI 90 measure can be found on the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228695355425.* Technical specifications for the CDC NHSN HAI measures can be found at CDC's NHSN website at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html.* Both websites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

5. Proposed Measure Removal Factors

While we are not proposing to remove any measures in this proposed rule, we are proposing to adopt a removal factor policy as part of our ongoing efforts to ensure that the HAC Reduction Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall burden and costs associated with the program. In addition, the adoption of measure removal factors would align the HAC Reduction Program with our other quality reporting and quality payment programs and help ensure consistency in our measure evaluation methodology across programs.

In the FY 2019 IPPS/LTCH PPS final rule, we updated considerations for removing measures from several CMS quality reporting and quality payment programs. Specifically, we finalized eight measure removal factors for the Hospital IQR Program (83 FR 41540 through 41544), the Hospital VBP Program (83 FR 41441 through 41446), the PCHQR Program (83 FR 41609 through 41611), and the LTCH QRP (83 FR 41625 through 41627).

We believe these removal factors are also appropriate for the HAC Reduction Program, and we believe that alignment among CMS quality programs is important to provide stakeholders with a clear, consistent, and transparent process. Therefore, to align with our other quality reporting and quality payment programs, we are proposing to adopt the following removal factors for the HAC Reduction Program:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures);
- Factor 2. Measure does not align with current clinical guidelines or practice;
- Factor 3. Measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 4. Measure performance or improvement does not result in better patient outcomes;
- Factor 5. Measure can be replaced by a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6. Measure collection or public reporting leads to negative unintended consequences other than patient harm;[402]
- Factor 7. Measure is not feasible to implement as specified; and
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.[403]

We note that these removal factors are considerations taken into account when deciding whether or not to remove measures, not firm requirements, and that we will propose to remove measures based on these factors on a case-by-case basis. We continue to believe that there may be circumstances in which a measure that meets one or more factors for removal should be retained regardless because the benefits of a measure can outweigh its drawbacks. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

6. Administrative Policies for the HAC Reduction Program for FY 2020 and Subsequent Years

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41475 through 41485), we discussed our previously finalized administrative polices for the HAC Reduction Program and adopted several HAC Reduction Program-specific policies for CDC NHSN HAI data collection and validation.

a. Data Collection Beginning CY 2020

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41475 through 41477), the HAC Reduction Program will assume responsibility for receiving CDC NHSN HAI data from the CDC beginning with CY 2020 (January 1, 2020) submissions. All reporting requirements, including, but not limited to, quarterly frequency, CDC collection system and deadlines, will remain constant from the current Hospital IQR Program requirements to aid continued hospital reporting through clear and consistent requirements. We refer readers to the Hospital IQR Program's prior years' rules for reference of these requirements[404] and to QualityNet for the current reporting requirements and deadlines.

Hospitals will continue to submit data through the CDC NHSN portal by selecting ''NHSN Reporting'' after signing in at: *https://sams.cdc.gov.* The HAC Reduction Program will receive the CDC NHSN data directly from the CDC instead of through the Hospital IQR Program as an intermediary. We note that some hospitals may not have locations that meet the CDC NHSN criteria for CLABSI or CAUTI reporting, and that some hospitals may perform so few procedures requiring surveillance under the Colon and Abdominal Hysterectomy SSI measure that the data may not be meaningful for public reporting or sufficiently reliable to be utilized for a program year. If a hospital does not have adequate locations or procedures, it should submit the Measure Exception Form to the HAC

[402] When there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns, CMS will take immediate action to remove a measure from the program and not wait for the annual rulemaking cycle. In such situations, we would promptly retire such measures followed by subsequent confirmation of the retirement in the next IPPS rulemaking. When we do so, we will notify hospitals and the public through the usual hospital and QIO communication channels used for the HAC Reduction Program, which include memo and email notification and QualityNet website articles and postings.

[403] We refer readers to the Hospital IQR Program's removal factors discussions in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for additional details on the removal factors and the rationale supporting them.

[404] FY 2011 IPPS/LTCH PPS final rule (75 FR 50223 through 50224); FY 2012 IPPS/LTCH PPS final rule (76 FR 51644 through 51645); FY 2013 IPPS/LTCH PPS final rule (77 FR 53539); FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822); FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262); FY 2016 IPPS/LTCH PPS final rule (80 FR 49710); FY 2017 IPPS/LTCH PPS final rule (81 FR 57173); FY 2018 IPPS/LTCH PPS final rule (82 FR 38398); FY 2019 IPPS/LTCH PPS final rule (83 FR 41607).

Reduction Program beginning on January 1, 2020. The IPPS Quality Reporting Programs Measure Exception Form is located using the link located on the QualityNet website under the Hospitals Inpatient > Hospital Inpatient Quality Reporting Program tab at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021.* As has been the case under the Hospital IQR Program, hospitals seeking an exception would submit this form at least annually to be considered.

We reiterate that no additional collection mechanisms are required for the CMS PSI 90 measure because it is a claims-based measure calculated using data submitted to CMS by hospitals for Medicare payment, and therefore imposes no additional administrative or reporting requirements on participating hospitals.

In this proposed rule, we are not proposing any updates to our previously finalized data collection processes.

b. Review and Correction of Claims Data and Chart-Abstracted CDC NHSN HAI Data Used in the HAC Reduction Program for FY 2020 and Subsequent Years

For the review and correction of claims data, hospitals are encouraged to ensure that their claims are accurate prior to the snapshot date, which is taken after the 90-day period following the last date of discharge used in the applicable period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50726 through 50727) and FY 2019 IPPS/LTCH PPS final rule (83 FR 41477 through 41478), we detailed the process for the review and correction of claims-based data, and we refer readers to those rules for more information on the process for the review and correction of claims-based data.

For the review and correction of chart-abstracted CDC NHSN HAI measures, we reiterate that hospitals can submit, review, and correct any of the chart-abstracted information for the full 4½ months after the end of the reporting quarter. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50726), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38270 through 38271), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41477 through 41478) for more information.

In this proposed rule, we are not proposing any change to our current administrative policies regarding the review and correction of claims data or chart-abstracted CDC NHSN HAI data.

7. Proposed Change to Validation Targeting Methodology and Clarifications Regarding Validation Processes

a. Summary of Existing Validation Processes

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), we adopted processes to validate the CDC NHSN HAI measure data used in the HAC Reduction Program because the Hospital IQR Program finalized its proposals to remove CDC NHSN HAI measures from its program. We finalized the HAC Reduction Program's processes to reflect, to the greatest extent possible, the processes previously established under the Hospital IQR Program. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), for detailed information on the following HAC Reduction Program validation processes:

- Measures Subject to Validation
- Educational Review Process
- Calculation of Confidence Intervals
- Application of Validation Scoring and Penalty
- Validation Period
- Data Accuracy and Completeness Acknowledgement

We also refer readers to the QualityNet website for more information regarding measure abstraction: *https://www.qualitynet.org/dcs/ContentServer?cid=%2012287762888808&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page.*

We would also like to remind stakeholders of the finalized validation periods for the HAC Reduction Program.

Finalized Validation Period for the HAC Reduction Program in FY 2023
[*Dates are subject to change]

Discharge Quarters by Fiscal Year (FY)	Current CDC NHSN HAI Submission Deadline*	Current CDC NHSN HAI Validation Templates*	Estimated CDAC[405] Record Request	Estimated Date Records Due to CDAC	Estimated Validation Completion
Q1 2020	08/15/2020				
Q2 2020	11/15/2020				
Q3 2020^	**02/15/2021**	**02/01/2021**	**02/28/2021**	**03/30/2021**	**06/15/2021**
Q4 2020^	**05/15/2021**	**05/01/2021**	**05/30/2021**	**06/29/2021**	**09/15/2021**
Q1 2021^	**08/15/2021**	**08/01/2021**	**08/30/2021**	**09/29/2021**	**12/15/2021**
Q2 2021^	**11/15/2021**	**11/01/2021**	**11/29/2021**	**12/29/2021**	**03/15/2022**
Q3 2021	02/15/2022				
Q4 2021	05/15/2022				

Bolded rows with dates in each column, denoted with the ^ symbol next to the date in the Discharge Quarter by Fiscal Year (FY) column, indicate the validation cycle for the FY.

In this proposed rule, we are proposing to change the number of hospitals selected under the validation targeting methodology and are providing two clarifications to this validation process.

b. Proposed Change to the Previously Finalized Validation Selection Methodology

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41480), we finalized our policy to select 200 additional hospitals for targeted validation and five targeting criteria.

While we are retaining the same targeting criteria that we finalized last year, we are proposing to change the number of hospitals targeted from exactly 200 hospitals to ''up to 200 hospitals.'' We believe this change is necessary to provide flexibility in the selection process for the HAC Reduction Program so that we can implement a targeting process for validation of chart-abstracted measures in both the Hospital IQR Program and HAC Reduction Program in a manner that does not unnecessarily subject hospitals to selection just to meet the 200 number. This proposed policy would allow us to only select hospitals that meet the targeting criteria and allow us to remove hospitals that do not have the requisite number of CDC NHSN HAI events from the targeted validation pool. We note that this will not affect the statistical reliability of the validation sample because statistical methodologies are only applied to data within hospitals for validation.

c. Clarifications to the Validation Selection Methodology

As discussed in section IV.I.7.a. of the preamble of this proposed rule, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), we finalized several proposals to implement validation of the CDC NHSN HAI measures in the HAC Reduction Program, in as similar a manner to the validation process used by the Hospital IQR Program as prudent. In this proposed rule, in addition to proposing to change the number of targeted hospitals from ''200'' to ''up to 200'', we also are clarifying our selection process for both the random and targeted sample of subsection (d) hospitals subject to HAC Reduction Program validation.

During the comment period for the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 41479), some commenters expressed concern that hospitals could now be selected for validation under both the Hospital IQR Program and the HAC Reduction Program during the same reporting period, thereby increasing the burden to selected hospitals. As we stated last year, one of the goals of our deduplication efforts has been and continues to be a reduction in provider burden. To that end and to allay stakeholder concerns, we are clarifying the provider selection process and reassuring providers that we will work to reduce validation burden to the greatest extent possible.

We are clarifying that the HAC Reduction Program, in conjunction with the Hospital IQR Program, will use an aggregated random sample selection methodology through which the validation team would select one pool of 400 subsection (d) hospitals for validation of chart-abstracted measures in both the Hospital IQR Program and HAC Reduction Program. The pool of 400 hospitals will be selected randomly and validated for both the CDC NHSN HAI measures for the HAC Reduction Program and the Hospital IQR Program's chart-abstracted measures. The HAC Reduction Program will include all subsection (d) hospitals, whereas the Hospital IQR Program will remove any subsection (d) hospital without an active notice of participation in the Hospital IQR Program (83 FR 41479).

This approach will ensure that the Programs' validation samples are selected at random and would avoid any perception associated with the selection of one program's sample before the other program's sample. We will begin using this selection process with Q3 CY 2020 infectious events, which is when the HAC Reduction Program is scheduled to begin its validation process. We refer readers to section VIII.A.11. of the preamble of this proposed rule for more information on the Hospital IQR Program's validation policies.

After the random selection process, an additional targeted [406] aggregated sample of up to 200 hospitals will be selected for the HAC Reduction and Hospital IQR Programs' validation processes using existing targeting criteria.

We also note that any nonsubstantive updates to the specifications for validation of chart-abstracted measures will be provided on the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?cid=%201228776288808&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page*. Further, any substantive changes, such as the measures validated, changes to passing confidence intervals, and the number of providers selected, will be proposed through notice-and-comment rulemaking.

We believe this clarification of our approach to the random selection of one pool of 400 hospitals and our proposal to select up to 200 targeted hospitals will avoid increasing provider burden because the total number of hospitals selected for validation is not increasing, nor are the measures that were subject to validation for the selected hospitals prior to deduplication.

Moreover, we do not anticipate any increased burden to hospitals because we are not increasing the number of cases selected for validation. For HAC Reduction Program validation, we will continue to select up to 40 cases annually from each hospital selected for validation (four CAUTI, four CLABSI, and two Colon and Abdominal Hysterectomy SSI per quarter; or four CDI, four MRSA, and two Colon and Abdominal Hysterectomy SSI per quarter). As we stated in the FY 2019 IPPS/LTCH PPS rulemaking, we intend this process to be as efficient as possible and we believe this clarification and our proposal help meet that expectation.

d. Proposed Clarification to Validation Filtering Methodology

As we discussed for the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53542), CMS has the option to target the sample selection to cases, referred to as candidate events, that are more likely to be true CDC NHSN HAIs events, or those that meet CDC NHSN HAI criteria. To better target true events for CDC NHSN HAI validation, we are proposing to clarify our approach for selecting CLABSI and CAUTI cases for chart-abstracted validation when CDC NHSN HAI validation that is currently performed under the Hospital IQR Program migrates to the HAC Reduction Program, beginning with the reporting of Q3 CY 2020 infections events. To date, our experience has shown us that many candidate cases selected for validation have all their positive cultures collected during the first or second day following admission and, as such, would be considered community onset events for CLABSI and CAUTI.[407] Therefore, we

[405] The CMS Clinical Data Abstraction Center (CDAC) performs the validation.

[406] We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41480), where we detailed the criteria for selecting additional hospitals for targeted validation.

[407] We refer readers to CDC guidance on this issue and the ''CLABSI Tool Display'' on the CDC website and on QualityNet, located at: *http://www.cdc.gov/nhsn/PDFs/pscManual/2PSC_IdentifyingHAIs_NHSNcurrent.pdf* and *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1140537256076*.

are proposing to clarify that we will eliminate these candidate CLABSI and CAUTI cases from the CDC NHSN HAI selection process prior to random case selection via a filtering method. The filtering method would eliminate any cases from the validation pool for which all positive blood or urine cultures were collected during the first or second day following admission. We estimate that, by implementing this proposed filtering method, the number of true events validated for CLABSI and CAUTI will increase without increasing the sample size, which will help us better understand the overreporting and underreporting of such events. This proposed approach is also in support of the recommendations provided by a recent HHS Office of Inspector General (OIG) report, which recommended that we make better use of analytics to ensure the integrity of hospital-reported quality data and the resulting payment adjustments by identifying potential gaming or other inaccurate reporting of quality data.[408]

A key rationale for this proposed approach is that we have found that the yield rate for CLABSI and CAUTI, which is defined as the ratio of the number of true CDC NHSN HAI events to the total sample size of candidate events, is low (13 percent for CLABSI and 9 percent for CAUTI, based on the FY 2017 validation sample). After applying the proposed filtering method to the FY 2017 sample, we estimated that the yield rate increased from 13 percent to 24 percent for CLABSI and from 9 percent to 17 percent for CAUTI. This increase will help CMS better understand the number of overreporting and underreporting of such events. A higher yield rate improves the power of the validation methodology, meaning that CMS could potentially select fewer cases for validation while still increasing the predictive power of the validation methodology. A potential reduction in the amount of cases selected for validation would decrease burden for hospitals.

In addition, because hospitals may now have fewer than four events each of CLABSI and CAUTI that meet validation filtering requirements, we expect a reduction in burden from some hospitals being required to submit three or fewer medical records as part of the validation process. We anticipate this filtering method to allow for both a richer data sample and reduced provider burden.

We also note that the agreement rates between hospital-reported MRSA and CDI events compared to events identified as infections by a trained CMS abstractor using a standardized protocol (77 FR 53548) have been lower than the agreement rates for CLABSI and CAUTI. Unlike the true event rate issue for CLABSI and CAUTI, we have determined that the lower overall agreement rates for MRSA and CDI is due to the overreporting of such events. This overreporting appears to be caused by missing or incomplete laboratory record information submitted by hospitals on the validation templates. As a result, we will provide additional training to hospitals regarding template completion and medical record submission with the hope of increasing hospital validation performance on MRSA and CDI measures.

Colon and Abdominal Hysterectomy SSI has a similarly low yield rate, and we have begun testing a filtering option to apply to Colon and Abdominal Hysterectomy SSI cases to increase the yield rate for that measure as well. We anticipate providing further guidance for Colon and Abdominal Hysterectomy SSI in future rulemaking cycles. In this proposed rule, we are not proposing any changes to the validation of Colon and Abdominal Hysterectomy SSI events.

8. HAC Reduction Program Scoring Methodology

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41485 through 41489), we finalized our proposal to remove domains from the HAC Reduction Program and simply assign equal weight to each measure for which a hospital has a measure score. As a result of this policy, we calculate each hospital's Total HAC Score as the equally weighted average of the hospital's measure scores. The table below displays the weights applied to each measure under this approach. All other aspects of the HAC Reduction Program scoring methodology remained the same, including the calculation of measure scores as Winsorized z-scores (FY 2017 IPPS/LTCH PPS final rule 81 FR 57022 through 57025), the determination of the 75th percentile Total HAC Score (83 FR 41480), and the determination of the worst-performing quartile (83 FR 41481 through 41482). In this proposed rule, we are not proposing any changes to this methodology.

WEIGHT APPLIED TO EACH MEASURE BY NUMBER OF MEASURES WITH MEASURE SCORE FOR HOSPITALS WITH AND WITHOUT A CMS PSI 90 SCORE UNDER EQUAL MEASURE WEIGHTS APPROACH

Number of CDC NHSN HAI measures with measure score	Weight applied to:	
	CMS PSI 90	Each CDC NHSN HAI measure
0	100.0	N/A.
1	50.0	50.0.
2	33.3	33.3.
3	25.0	25.0.
4	20.0	20.0.
5	16.7	16.7.
Any number	N/A	100.0 (equally divided among each CDC NHSN HAI measure with measure score).

9. Scoring Calculations Review and Correction Period

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41484), we renamed the annual 30-day review and correction period to the ''Scoring Calculations Review and Correction Period.'' The purpose of the annual 30-day review and corrections period is to allow hospitals to review the calculation of their HAC Reduction Program scores.

The HAC Reduction Program will continue to provide hospitals with annual confidential hospital-specific reports and discharge level information used in the calculation of their Total HAC Scores via the QualityNet Secure

[408] April 2017 OIG report titled ''CMS Validated Hospital Inpatient Quality Reporting Program Data, But Should Use Additional Tools to Identify Gaming.'' Available at: *https://www.oig.hhs.gov/oei/reports/oei-01–15–00320.asp.*

Portal. Hospitals must register at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138115992011* for a QualityNet Secure Portal account in order to access their annual hospital-specific reports.

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50725 through 50728), hospitals have a period of 30 days after the information is posted to the QualityNet Secure Portal to review their HAC Reduction Program scores, submit questions about the calculation of their results, and request corrections for their HAC Reduction Program scores prior to public reporting. Hospitals may use the 30-day Scoring Calculations Review and Correction Period to request corrections to the following information prior to public reporting:

- CMS PSI 90 measure score;
- CMS PSI 90 measure result and Winsorized measure result;
- CLABSI measure score;
- CAUTI measure score;
- Colon and Abdominal Hysterectomy SSI measure score;
- MRSA Bacteremia measure score;
- CDI measure score; and
- Total HAC Score.

As we clarified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38270 through 38271), this 30-day period is not an opportunity for hospitals to submit additional corrections related to the underlying claims data for the CMS PSI 90, or to add new claims to the data extract used to calculate the results. Hospitals have an opportunity to review and correct claims and CDC NHSN HAI data used in the HAC Reduction Program as detailed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50726 through 50727), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38270 through 38271), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41477 through 41478).

In this proposed rule, we are not proposing any changes our policies regarding the scoring calculations review and correction period.

10. Proposed Applicable Period for FY 2022 Program Year

In the FY 2018 IPPS/LTCH PPS final rule, we finalized the applicable period for the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) as the 24-month period from July 1, 2016 through June 30, 2018. For the CDC NHSN HAI measures (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), we finalized the use of data from CYs 2017 and 2018, that is, January 1, 2017 through December 31, 2018, for the FY 2020 program.

Consistent with the definition specified at § 412.170, we are proposing to adopt the applicable period for the FY 2022 HAC Reduction Program for the CMS PSI 90 as the 24-month period from July 1, 2018 through June 30, 2020, and the applicable period for CDC NHSN HAI measures as the 24-month period from January 1, 2019 through December 31, 2020.

11. Limitation on Administrative and Judicial Review

Section 1886(p)(7) of the Act, as codified at 42 CFR 412.172(g), provides that there will be no administrative or judicial review under section 1869 of the Act, under section 1878 of the Act, or otherwise for any of the following:

- The criteria describing an applicable hospital in paragraph 1886(p)(2)(A) of the Act;
- The specification of hospital acquired conditions under paragraph 1886(p)(3) of the Act;
- The specification of the applicable period under paragraph 1886(p)(4) of the Act;
- The provision of reports to applicable hospitals under paragraph 1886(p)(5) of the Act; and
- The information made available to the public under paragraph 1886(p)(6) of the Act.

For additional information, we refer readers to FY 2014 IPPS/LTCH PPS final rule (78 FR 50729) and FY 2015 IPPS/LTCH PPS final rule (79 FR 50100).

12. Proposed Regulatory Updates (42 CFR 412.172)

We are proposing to update 42 CFR 412.172(f)(2) and (4) to reflect current policies and align across our quality programs. We are proposing these updates to remove references to domains, which were removed from the scoring methodology beginning with the FY 2020 calculation. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41485 through 41489) for a discussion of the removal of domains from the HAC Reduction Program and more information about the equal weighting scoring methodology.

J. Payments for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272), establishes a methodology for determining Medicare payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days. The provisions of section 1886(h) of the Act are implemented in regulations at 42 CFR 413.75 through 413.83.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulation regarding the calculation of this additional payment is located at 42 CFR 412.105. The hospital's IME adjustment applied to the MS–DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit (that is, a cap) on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before

December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

Section 5504 of the Affordable Care Act (Pub. L. 111–148) made a number of statutory changes relating to the determination of a hospital's FTE resident count for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances. Regulations implementing these changes are discussed in the November 24, 2010 final rule (75 FR 72133) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53416).

2. Proposed Policy Changes Related to Critical Access Hospitals (CAHs) as Nonproviders for Direct GME and IME Payment Purposes

Under the regulation governing direct GME payments to nonprovider sites at 42 CFR 413.78(g) (and the corresponding IME regulation at 42 CFR 412.105(f)(1)(ii)(E)), a hospital can include residents training in a nonprovider setting in its FTE count if the hospital incurs the residents' salaries and fringe benefits while the residents are training at that site, in addition to other requirements. Under current policy, critical access hospitals (CAHs) that train residents in approved residency training programs are paid 101 percent of the reasonable costs for any costs they incur associated with training residents in approved programs, consistent with the CAH payment regulations at 42 CFR 413.70. We have heard concerns related to CMS' current policy that CAHs are not considered nonprovider sites for purposes of direct GME and IME payments, including the concern that CMS' current policy is creating barriers to training residents in rural areas, thereby also hindering efforts to increase the practice of physicians in rural areas. We previously heard concerns that not considering CAHs to be nonprovider sites would reduce training in rural and underserved areas and affect primary care and community-based residency training programs, such as family medicine, which train in those areas (78 FR 50737). Stakeholders also raised concerns that not considering CAHs to be nonprovider sites would hinder collaborative efforts between hospitals and CAHs to recruit and retain physicians in rural areas (78 FR 50737) and that some CAHs may be too small to support residency training programs or may not be in a financial position to incur the costs associated with residency training programs (78 FR 50738). In light of these concerns, we have reexamined the statutory language associated with this policy, issues raised in prior rulemaking related to this policy, and the intent of the changes made by section 5504 of the Affordable Care Act. As a result, we are proposing to modify our policy, such that a hospital could include residents training in a CAH in its FTE count as long as the nonprovider setting requirements at 42 CFR 413.78(g) are met. Below we discuss our proposal for this policy change.

We adopted our current GME payment policy regarding nonprovider settings and CAHs in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50734 through 50739). Prior to this time, we allowed a CAH the option to either function as a nonhospital site or to incur costs for training residents in an approved program and be paid 101 percent of the reasonable costs for any costs associated with training residents in an approved program. In part, our policy was driven by how we have regarded nonhospital settings and the unique nature of CAHs. Although we generally had used the term ''nonhospital'' to describe the training sites in which time spent by residents training outside of the hospital setting may be counted for both direct GME and IME payment purposes, we acknowledged in the FY 2014 IPPS/LTCH PPS final rule that we sometimes used the terms ''nonhospital'' and ''nonprovider'' interchangeably (78 FR 50735). We considered that a CAH is a unique facility that, by definition, is not always a hospital and noted that, because a CAH is generally not considered a ''hospital'' under section 1861(e) of the Act, a CAH could be treated as a nonhospital site for GME purposes (78 FR 50735).

Section 5504(a) of the Affordable Care Act amended sections 1886(d)(5)(B)(iv)(II) and 1886(h)(4)(E) of the Act, on a prospective basis, to further address the setting in which time spent by residents training outside of the hospital setting may be counted for both direct GME and IME payment purposes. In particular, the statute was amended to reference a ''nonprovider.'' As a result of this legislative change and because a CAH is defined as a ''provider of services'' under section 1861(u) of the Act, we finalized our current policy, effective for portions of cost reporting periods occurring on or after October 1, 2013.

Section 5504 of the Affordable Care Act made several changes to the requirements a hospital must meet in order to include residents training in a nonprovider setting in its FTE count. As we noted in prior rulemaking, these changes include the requirement that a hospital need only incur residents' salaries and fringe benefits in order to count the residents as opposed to incurring ''all or substantially all'' of the costs of the training at the nonprovider site and the ability for more than one hospital to count FTE residents training at a single nonprovider site (75 FR 72136 through 72139). We believe these changes were intended to promote the training of residents at sites outside of the IPPS hospital setting, many of which provide access to care for patients in rural and underserved areas. Furthermore, we reassessed and agree with prior comments we have received stating that the intent of section 5504 was to reduce the administrative burden associated with counting residency training time in settings engaged in patient care outside of the IPPS hospital setting (78 FR 50736). Therefore, we believe that, to the extent possible, in accordance with current statutory language, it is important to support residency training in rural and underserved areas, including residency training at CAHs.

While a CAH is considered a ''provider of services'' under section 1861(u) of the Act, we acknowledge that the term ''nonprovider'' is not explicitly defined in the statute. Furthermore, section 1861(e) of the Act, which states in part that the term ''hospital'' does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1) of the Act), underscores the sometimes ambiguous status of CAHs. We believe that the lack of both an explicit statutory definition of ''nonprovider'' and a definitive determination as to whether a CAH is considered a hospital along with the fact that a CAH is a facility primarily engaged in patient care (we refer readers to section 1886(h)(5)(K) of the Act which states that the term ''nonprovider setting that is primarily engaged in furnishing patient care'' means a nonprovider setting in which the primary activity is the care and treatment of patients, as defined by the Secretary), provides flexibility within the current statutory language to consider a CAH as a ''nonprovider'' setting for direct GME and IME payment purposes.

Therefore, in order to support the training of residents in rural and underserved areas, we are proposing that, effective with portions of cost

reporting periods beginning October 1, 2019, a hospital may include FTE residents training at a CAH in its FTE count as long as it meets the nonprovider setting requirements currently included at 42 CFR 412.105(f)(1)(ii)(E) and 413.78(g). We are not proposing to change our policy with respect to CAHs incurring the costs of training residents. That is, a CAH may continue to incur the costs of training residents in an approved residency training program(s) and receive payment based on 101 percent of the reasonable costs for these training costs. If this proposal is finalized, CMS will work closely with HRSA and the Federal Office of Rural Health Policy to communicate the increased regulatory flexibility to CAHs as well as existing residency programs and the options it affords for increasing rural residency training. We are seeking public comments on this proposed policy change.

3. Notice of Closure of Teaching Hospital and Opportunity To Apply for Available Slots

a. Background

Section 5506 of the Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the ''Affordable Care Act''), authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Specifically, section 5506 of the Affordable Care Act amended the Act by adding subsection (vi) to section 1886(h)(4)(H) of the Act and modifying language at section 1886(d)(5)(B)(v) of the Act, to instruct the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the FTE resident caps in teaching hospitals that closed ''on or after a date that is 2 years before the date of enactment'' (that is, March 23, 2008). In the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR 72212), we established regulations at 42 CFR 413.79(o) and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from the hospital that closed. We made certain modifications to those regulations in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134). The procedures we established apply both to teaching hospitals that closed on or after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that close after August 3, 2010.

b. Notice of Closure of Good Samaritan Hospital Located in Dayton, OH and the Application Process—Round 14

CMS has learned of the closure of Good Samaritan Hospital, located in Dayton, OH (CCN 360052). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round of the section 5506 application and selection process. This round will be the 14th round (''Round 14'') of the application and selection process. The table below contains the identifying information and IME and direct GME FTE resident caps for the closed teaching hospital, which is part of the Round 14 application process under section 5506 of the Affordable Care Act.

CCN	Provider name	City and state	CBSA code	Terminating date	IME FTE resident cap (including +/− MMA sec. 422 [1])	Direct GME FTE resident cap (including +/− MMA sec. 422 [1])
360052	Good Samaritan Hospital.	Dayton, OH	19380	July 23, 2018	55.60 + 7.00 sec. 422 increase = 62.60.[2]	58.89 + 3.14 sec. 422 increase = 62.03.[3]

[1] Section 422 of the MMA, Public Law 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.

[2] Good Samaritan Hospital's 1996 IME FTE resident cap is 55.60. Under section 422 of the MMA, the hospital received an increase of 7.00 to its IME FTE resident cap: 55.60 + 7.00 = 62.60.

[3] Good Samaritan Hospital's 1996 direct GME FTE resident cap is 58.89. Under section 422 of the MMA, the hospital received an increase of 3.14 to its direct GME FTE resident cap: 58.89 + 3.14 = 62.03.

c. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notice to the public of a hospital closure (77 FR 53436). Therefore, hospitals that wish to apply for and receive slots from the FTE resident caps of closed Good Samaritan Hospital, located in Dayton, OH, must submit applications (Section 5506 Application Form posted on Direct Graduate Medical Education (DGME) website as noted at the end of this section) directly to the CMS Central Office no later than July 22, 2019. The mailing address for the CMS Central Office is included on the application form. Applications must be received by the CMS Central Office by the July 22, 2019 deadline date. It is *not* sufficient for applications to be postmarked by this date.

After an applying hospital sends a hard copy of a section 5506 slot application to the CMS Central Office mailing address, the hospital is encouraged to notify the CMS Central Office of the mailed application by sending an email to: *ACA5506application@cms.hhs.gov.* In the email, the hospital should state: ''On behalf of [insert hospital name and Medicare CCN#], I, [insert your name], am sending this email to notify CMS that I have mailed to CMS a hard copy of a section 5506 application under Round 14 due to the closure of Good Samaritan Hospital. If you have any questions, please contact me at [insert phone number] or [insert your email address].'' An applying hospital should *not* attach an electronic copy of the application to the email. The email will only serve to notify the CMS Central Office to expect a hard copy application that is being mailed to the CMS Central Office.

We have not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received by the deadline and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Direct Graduate Medical Education (DGME) website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.html* to download a copy of the section 5506 application form (Section 5506 Application Form) that hospitals must use to apply for slots under section 5506 of the Affordable Care Act. Hospitals should also access this same

website for a list of additional section 5506 guidelines for the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

K. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed below). Section 15003 also required that, no later than 120 days after enactment of Public Law 114–255, the Secretary had to issue a solicitation for applications to select additional hospitals to participate in the demonstration program for the second 5 years of the 10-year extension period, so long as the maximum number of 30 hospitals stipulated by Public Law 114–148 was not exceeded. In this proposed rule, we are providing a description of the provisions of section 15003 of Public Law 114–255, our final policies for implementation, and the finalized budget neutrality methodology for the extension period authorized by section 15003 of Public Law 114–255. We are including a discussion of the budget neutrality methodology used in previous final rules for periods prior to the extension period, as well as for this upcoming fiscal year. In addition, we will provide an update on the reconciliation of actual and estimated costs of the demonstration for FYs 2014 and 2015.

2. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A of Public Law 108–173 required a 5-year period of performance. Subsequently, sections 3123 and 10313 of Public Law 111–148 required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. Public Law 111–148 required the Secretary to provide for the continued participation of rural community hospitals in the demonstration program during the 5-year extension period, in the case of a rural community hospital participating in the demonstration program as of the last day of the initial 5-year period, unless the hospital made an election to discontinue participation. In addition, Public Law 111–148 limited the number of hospitals participating to no more than 30. We refer readers to previous final rules for a summary of the selection and participation of these hospitals. Starting from December 2014 and extending through December 2016, the 21 hospitals that were still participating in the demonstration ended their scheduled periods of performance on a rolling basis, respectively, according to the end dates of the hospitals' cost report periods.

3. Provisions of the 21st Century Cures Act (Pub. L. 114–255) and Finalized Policies for Implementation

a. Statutory Provisions

As stated earlier, section 15003 of Public Law 114–255 further amended section 410A of Public Law 108–173 to require the Secretary to conduct the Rural Community Hospital Demonstration for a 10-year extension period (in place of the 5-year extension period required by Pub. L. 111–148), beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Thus, the Secretary is required to conduct the demonstration for an additional 5-year period. Specifically, section 15003 of Public Law 114–255 amended section 410A(g)(4) of Public Law 108–173 to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary shall provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital makes an election, in such form and manner as the Secretary may specify, to discontinue participation. Furthermore, section 15003 of Public Law 114–255 added subsection (g)(5) to section 410A of Public Law 108–173 to require that, during the second 5 years of the 10-year extension period, the Secretary shall apply the provisions of section 410A(g)(4) of Public Law 108–173 to rural community hospitals that are not described in subsection (g)(4) but that were participating in the demonstration as of December 30, 2014, in a similar manner as such provisions apply to hospitals described in subsection (g)(4).

In addition, section 15003 of Public Law 114–255 amended section 410A of Public Law 108–173 to add paragraph (g)(6)(A) which requires that the Secretary issue a solicitation for applications no later than 120 days after enactment of paragraph (g)(6) to select additional rural community hospitals located in any State to participate in the demonstration program for the second 5 years of the 10-year extension period, without exceeding the maximum number of hospitals (that is, 30) permitted under section 410A(g)(3) of Pub. L. 108–173 (as amended by Public Law 111–148). Section 410A(g)(6)(B) provides that, in determining which hospitals submitting an application pursuant to this solicitation are to be selected for participation in the demonstration, the Secretary must give priority to rural community hospitals located in one of the 20 States with the lowest population densities, as determined using the 2015 Statistical Abstract of the United States. The Secretary may also consider closures of hospitals located in rural areas in the State in which an applicant hospital is located during the 5-year period immediately preceding the date of enactment of Public Law 114–255 (December 13, 2016), as well as the population density of the State in which the rural community hospital is located.

(b) Terms of Participation for the Extension Period Authorized by Public Law 114–255

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38280), we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under

the demonstration for those previously participating hospitals choosing to participate in the second 5-year extension period. According to our finalized policy, each previously participating hospital began the second 5 years of the 10-year extension period and payment for services provided under the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Pub. L. 114–255) on the date immediately after the period of performance ended under the first 5-year extension period.

Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by Public Law 111–148 elected to continue in the second 5-year extension period for the full second 5-year extension period. (Of the four hospitals that did not elect to continue participating, three hospitals converted to CAH status during the time period of the second 5-year extension period.) Therefore, the 5-year period of performance for each of these hospitals started on dates beginning May 1, 2015 and extending through January 1, 2017. On November 20, 2017, we announced that, as a result of the solicitation issued earlier in the year responding to the requirement in Public Law 114–255, 13 additional hospitals were selected to participate in the demonstration in addition to these 17 hospitals continuing participation from the first 5-year extension period. (Hereafter, these two groups are referred to as ''newly participating'' and ''previously participating'' hospitals, respectively.) In addition, we announced that each of these newly participating hospitals would begin its 5-year period of participation effective with the start of the first cost reporting period on or after October 1, 2017. One of the hospitals selected from the solicitation in 2017 withdrew from the demonstration program, prior to beginning participation in the demonstration on July 1, 2018. Therefore, 29 hospitals participated in the demonstration in FYs 2018 and 2019, and are scheduled to participate in FY 2020.

4. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of Public Law 108–173 requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, made it extremely unlikely that this demonstration program could be held to budget neutrality under the methodology normally used to calculate it—that is, cost-based payments to participating small rural hospitals were likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. In addition, a rural community hospital's participation in this demonstration program would be unlikely to yield benefits to the participants if budget neutrality were to be implemented by reducing other payments for these same hospitals. Therefore, in the 12 IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (A different methodology was applied for FY 2017.) As we discussed in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

b. Methodology Used in Previous Final Rules for Periods Prior to the Extension Period Authorized by the 21st Century Cures Act (Pub. L. 114–255)

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year, differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. (We note that we have calculated this difference for FYs 2005 through 2013 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.)

c. Budget Neutrality Methodology for the Extension Period Authorized by the 21st Century Cures Act (Pub. L. 114–255)

(1) General Approach

We finalized our budget neutrality methodology for periods of participation under the second 5 years of the 10-year extension period in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38285 through 38287). Similar to previous

years, we stated in this rule, as well as in the FY 2019 IPPS/LTCH PPS proposed and final rules (83 FR 20444 and 41503, respectively) that we would incorporate an estimate of the costs of the demonstration, generally determined from historical, ''as submitted'' cost reports for the participating hospitals and appropriate update factors, into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In addition, we stated that we would continue to apply our general policy from previous years of including, as a second component to the budget neutrality offset amount, the amount by which the actual costs of the demonstration for an earlier, given year (as determined from finalized cost reports when available) differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year.

In the FY 2018 IPPS/LTCH PPS final rule and FY 2019 IPPS/LTCH PPS proposed and final rules, we described several distinct components to the budget neutrality offset amount for the specific fiscal years of the extension period authorized by Public Law 114–255.

- We will include a component to our overall methodology similar to previous years, according to which an estimate of the costs of the demonstration for both previously and newly participating hospitals for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In the FY 2019 IPPS final rule (83 FR 41506), we included such an estimate of the costs of the demonstration for each of FYs 2018 and 2019 into the budget neutrality offset amount for FY 2019. In this proposed rule, we are including an estimate of the costs of the demonstration for FY 2020.
- Similar to previous years, we will continue to implement the policy of determining the difference between the actual costs of the demonstration as determined from finalized cost reports for a given fiscal year and the estimated costs indicated in the corresponding year's final rule, and including that difference as a positive or negative adjustment in the upcoming year's final rule. (For each previously participating hospital that has decided to participate in the second 5 years of the 10-year extension period, the cost-based payment methodology under the demonstration began on the date immediately following the end date of its period of performance for the first 5-year extension period. In addition, for previously participating hospitals that converted to CAH status during the time period of the second 5-year extension period, the demonstration payment methodology was applied to the date following the end date of its period of performance for the first extension period to the date of conversion). Therefore, for cost reporting periods starting in FYs 2015, 2016, and 2017, we will use available finalized cost reports that detail the actual costs of the demonstration for each of these fiscal years and incorporate these amounts into the budget neutrality calculation.

In this proposed rule, we are identifying the amount of the difference between actual and estimated costs based on finalized cost reports for FY 2014; and, in addition, we are proposing that if finalized cost reports are available we will include the amount for FY 2015 in the budget neutrality offset adjustment to be applied to the national IPPS rates for FY 2020. In future IPPS rules, we will continue this reconciliation, calculating the difference between actual and estimated costs for the remaining years of the first extension period and, as described above, the additional years of the demonstration under the second extension period, applying this difference to the budget neutrality offset adjustments identified in future years' final rules.

(2) Methodology for Estimating Demonstration Costs for FY 2020

We are using a methodology similar to previous years, according to which an estimate of the costs of the demonstration for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year, that is, FY 2020. The methodology for calculating the amount for FY 2020 will proceed according to the following steps:

Step 1: For each of the 29 participating hospitals, we will identify the reasonable cost amount calculated under the reasonable cost-based methodology for covered inpatient hospital services, including swing beds, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. (For each of these hospitals, these ''as submitted'' cost reports are those with cost report period end dates in CY 2017. We note that, for 3 of these hospitals, the 5-year participation authorized by Pub. L. 114–255 will end prior to the end of FY 2020. Therefore, consistent with previous practice, we will prorate the cost amounts for these hospitals by the fraction of total months in the demonstration period of participation that fall within FY 2020 out of the total of 12 months in the fiscal year. For example, for a hospital whose period of performance ends June 30, 2020, this prorating factor is .75. We will sum these hospital-specific amounts to arrive at a total general amount representing the costs for covered inpatient hospital services, including swing beds, across the 29 participating hospitals.

Then, we will multiply this amount by the FYs 2018, 2019 and 2020 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. The result for each participating hospital will be the general estimated reasonable cost amount for covered inpatient hospital services for FY 2020.

Consistent with our methods in previous years for formulating this estimate, we will apply the IPPS market basket percentage increases for FYs 2018 through 2020 to the applicable estimated reasonable cost amounts (described above) in order to model the estimated FY 2020 reasonable cost amount under the demonstration. We believe that the IPPS market basket percentage increases appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved.

Step 2: For each of the participating hospitals, we identify the estimated amount that would otherwise be paid in FY 2020 under applicable Medicare payment methodologies for covered inpatient hospital services, including swing beds (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. (Also, similar to step 1, we are prorating the amounts for hospitals whose period of participation ends during FY 2020 by the fraction of total months in the demonstration period of participation for the hospital that falls within FY 2020 out of the total of 12 months in the fiscal year). We will sum these hospital-specific amounts, and, in turn, multiply this sum by the FYs 2018, 2019 and 2020 IPPS applicable percentage increases. This methodology differs from Step 1, in which we apply the market basket percentage increases to the hospitals' applicable estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments constitute the majority of payments that would otherwise be made without the demonstration and the

applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Step 3: We will subtract the amount derived in Step 2 from the amount derived in Step 1. According to our methodology, the resulting amount indicates the total difference for the 29 hospitals (for covered inpatient hospital services, including swing beds), which will be the general estimated amount of the costs of the demonstration for FY 2020.

For this proposed rule, the resulting amount is $61,970,567, which we are proposing to include in the budget neutrality offset adjustment for FY 2020. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical update factors for cost and payment. If updated data become available prior to the FY 2020 IPPS/LTCH PPS final rule, we will use them as appropriate to estimate the costs for the demonstration program for FY 2020 in accordance with our methodology for determining the budget neutrality estimate. Therefore, the estimated budget neutrality offset amount may change in the final rule, depending on the availability of updated data.

(3) Reconciling Actual and Estimated Costs of the Demonstration for Previous Years (2014 and 2015)

As described earlier, we have calculated the difference for FYs 2005 through 2013 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years. In this proposed rule, we are identifying the difference between the total cost of the demonstration as indicated on finalized FY 2014 cost reports and the estimates for the costs of the demonstration for that year's final rule, and we are proposing to adjust the current year's budget neutrality amount by the amount identified. If any information relevant to the determination of these amounts (for example, a cost report reopening) would necessitate a revision of these amounts, we will make the appropriate change and include the determination in the FY 2020 IPPS/LTCH PPS final rule. Furthermore, if the needed costs reports are available in time for the FY 2020 IPPS/LTCH PPS final rule, we also will identify the difference between the total cost of the demonstration based on finalized FY 2015 cost reports and the estimates for the costs of the demonstration for that year, and incorporate that amount into the budget neutrality offset amount for FY 2020.

Currently, finalized cost reports are available for the 22 hospitals that completed a cost reporting period beginning in FY 2014 according to the demonstration's reasonable cost-based payment methodology. The actual costs of the demonstration for FY 2014 (that is, the amount from finalized cost reports for the 22 hospitals that were paid under the demonstration reasonable cost-based payment methodology for cost reporting periods with start dates during FY 2014), fell short of the estimated amount that was finalized in the FY 2014 IPPS/LTCH final rule for FY 2014 by $14,932,060.

We note that the amounts identified for the actual cost of the demonstration, determined from finalized cost reports, is less than the amount that was identified in the final rule for the respective year. Therefore, in keeping with previous policy finalized in situations when the costs of the demonstration fell short of the amount estimated in the corresponding year's final rule, we will be including this component as a negative adjustment to the budget neutrality offset amount for the current fiscal year.

(4) Total Proposed Budget Neutrality Offset Amount for FY 2020

Therefore, for this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to incorporate the following components into the calculation of the total budget neutrality offset for FY 2020:

- The amount determined under section IV.K.4.c.(2) of the preamble of this proposed rule, representing the difference applicable to FY 2020 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration to the 29 participating hospitals for covered inpatient hospital services and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $61,970,567.
- The amount determined under section IV.K.4.c.(3) of the preamble of this proposed rule according to which the actual costs of the demonstration for FY 2014 for the 22 hospitals that completed a cost reporting period beginning in FY 2014 differ from the estimated amount that was incorporated into the budget neutrality offset amount for FY 2014 in the FY 2014 IPPS/LTCH PPS final rule. Analysis of this set of cost reports shows that the actual costs of the demonstration fell short of the estimated amount finalized in the FY 2014 IPPS/LTCH PPS final rule by $14,932,060. In keeping with previously finalized policy, we are proposing to apply this difference, according to which the actual costs of the demonstration for FY 2014 fell short of the estimated amount determined in the final rule for that fiscal year by reducing the budget neutrality offset amount for FY 2020 by this amount.

Therefore, for FY 2020, the proposed total budget neutrality offset amount that we will be applying is the estimated amount for FY 2020 (that is, $61,970,567) minus the amount by which the actual costs of the demonstration fell short of the estimated amount for FY 2014 (that is, $14,932,060). This total is $47,038,507. If updated data become available prior to the FY 2020 IPPS/LTCH PPS final rule, we would use them to the extent appropriate to determine the budget neutrality offset amount for FY 2020. Therefore, the amount of the budget neutrality offset amount may change in the FY 2020 IPPS/LTCH PPS final rule. Furthermore, if the needed costs reports are available in time for the FY 2020 IPPS/LTCH PPS final rule, we also will identify the difference between the total cost of the demonstration based on finalized FY 2015 cost reports and the estimates for the costs of the demonstration for that year, and incorporate that amount into the final budget neutrality offset amount for FY 2020.

V. Proposed Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for

almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under §§ 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Proposed Annual Update for FY 2020

The proposed annual update to the national capital Federal rate, as provided for in 42 CFR 412.308(c), for FY 2020 is discussed in section III. of the Addendum to this FY 2020 IPPS/LTCH PPS proposed rule.

In section II.D. of the preamble of this FY 2020 IPPS/LTCH PPS proposed rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the adjustment to the standardized amount under section 1886(d) of the Act that we are proposing for FY 2020, in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA. Because these provisions require us to make an adjustment only to the operating IPPS standardized amount, we are not proposing to make a similar adjustment to the national capital Federal rate (or to the hospital-specific rates).

VI. Proposed Changes for Hospitals Excluded From the IPPS

A. Proposed Rate-of-Increase in Payments to Excluded Hospitals for FY 2020

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, and RNHCIs. Consistent with the regulations at §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FYs 2014 and 2015 IPPS/LTCH PPS final rules (78 FR 50747 through 50748 and 79 FR 50156 through 50157, respectively), we adopted a policy of

using the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2014 and subsequent fiscal years for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. However, in the FY 2018 IPPS/LTCH PPS final rule, we rebased and revised the IPPS operating basket to a 2014 base year, effective for FY 2018 and subsequent years (82 FR 38158 through 38175), and finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent years. Accordingly, for FY 2020, the rate-of-increase percentage to be applied to the target amount for these hospitals would be the FY 2020 percentage increase in the 2014-based IPPS operating market basket.

For this FY 2020 IPPS/LTCH PPS proposed rule, based on IGI's 2018 fourth quarter forecast, we estimated that the 2014-based IPPS operating market basket update for FY 2020 would be 3.2 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2020 rate-of-increase percentage that would be applied to the FY 2019 target amounts in order to calculate the FY 2020 target amounts for children's hospitals, cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be 3.2 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we are proposing that if more recent data become available for the final rule, we would use them to calculate the final IPPS operating market basket update for FY 2020.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4). (For additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).) Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under section 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2020, in accordance with § 412.22(i) and § 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2020, the proposed update to the target amount for long-term care neoplastic disease hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for FY 2020, which would be equal to the percentage increase in the hospital market basket index, which is estimated to be the percentage increase in the 2014-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2020 is 3.2 percent, which is based on IGI's 2018 fourth quarter forecast. Furthermore, we are proposing that if more recent data become available for the final rule, we would use that updated data to calculate the IPPS operating market basket update for FY 2020.

B. Request for Public Comments on Methodologies and Requirements for TEFRA Adjustments to the Rate-of-Increase Ceiling

1. General Background

Section 1886(b) of the Act, as amended by the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, establishes a ceiling on the allowable rate of increase in hospital inpatient operating costs per discharge applicable to cost reporting periods beginning on or after October 1, 1982. However, effective with cost reporting periods beginning on or after October 1, 1983, most hospitals are paid under the prospective payment system (PPS) as described in section 1886(d) of the Act, 42 CFR part 412, and Chapter 28 of the Provider Reimbursement Manual (PRM) (CMS Pub. 15–1). Currently, hospitals that are paid under TEFRA include cancer hospitals (11 qualified by statute under section 1886(d)(1)(B)(v) of the Act), children's hospitals, and hospitals outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands). Under certain circumstances, CMS may provide for an adjustment to the rate-of-increase ceiling or may assign a new base period.

Medicare payment for inpatient hospital services under the TEFRA system is made on a reasonable cost basis, as noted above, subject to a limit or ceiling. The ceiling is determined from a hospital's target amount per discharge updated from its base year. Specifically, a hospital's TEFRA target amount per discharge is determined from its total Medicare inpatient operating costs per Medicare discharge in its base year. This target amount per discharge is updated each year for inflation based on the IPPS operating market basket increase. Multiplying the TEFRA target amount per discharge by the Medicare discharges in a particular cost reporting period produces the maximum amount (the ceiling) Medicare will pay the hospital for inpatient hospital services. In other words, under the TEFRA system, Medicare payment is the lesser of the reasonable costs incurred or the ceiling amount. If a hospital's inpatient operating costs exceed the ceiling in a cost reporting period, section 1886(b)(4)(A)(i) of the Act and implementing regulations at § 413.40 allow hospitals paid under the TEFRA system to request adjustments to increase their Medicare payment limits (that is, their ceiling) or to request a new base year (a permanent revised TEFRA target amount per discharge for determining the ceiling) to account for certain factors such as a significant change in services or patient population.

2. TEFRA Adjustment Requests

Under the regulations at 42 CFR 413.40(g), if a hospital's inpatient operating costs exceed the ceiling in a cost reporting period, hospitals may request an increase to their Medicare payment limits (that is, their ceiling) to account for cost distortions between the base year and current year. Section 3004.1 of the PRM states that distortions

in inpatient operating costs resulting in noncomparability of the cost reporting periods are generally the result of extraordinary circumstances, an increase in the average length of stay of Medicare patients, or changes in the volume or intensity of direct patient care services. Section 3004 of the PRM provides extensive examples of noncomparability of cost reporting periods due to direct patient care changes with calculations for increases of average length of stay, changes in the intensity of care, as well as for additions/deletions of services. These examples were developed many years ago to assist providers in filing an adjustment request and to provide guidance to MACs when reviewing and evaluating a provider's adjustment request. The examples emphasize that the methodologies used to determine the amount of the adjustment are based on comparisons between the base year costs and current year costs. To receive an adjustment to its ceiling, the provider must demonstrate that the increased Medicare costs are reasonable, related to direct patient care services, attributable to the circumstances specified, separately identified by the hospital, verified by the contractor, and tie to costs quantified in its cost report. In some cases, an adjustment may be adopted permanently and reflected in the hospital's ceiling in subsequent cost reporting periods.

The delivery of direct patient care services, as well as the cost report form and instructions, have evolved since the guidance and examples currently in section 3004 of the PRM (Pub. 15–1) were originally developed. In this proposed rule, we are soliciting public comments, suggestions, and recommendations regarding the methodologies and examples provided in section 3004 of the PRM to determine an appropriate adjustment amount, considering the current environment facing providers paid by Medicare under the TEFRA system.

As noted above, under 42 CFR 413.40(i), hospitals can request a permanent change to their ceiling by requesting a new base year for determining their target amount per discharge. In accordance with 42 CFR 413.40(i)(1)(i)(B), this process is meant to account for substantial and permanent changes in furnishing patient care services since the base period, and, as such, the requirements are stringent. Historically, CMS has rarely authorized assignment of a new base year period because the adjustment mechanism discussed above is meant to address most situations where there is distortion in costs between the base year and the current period and providers seldom meet the criteria for a new base period. We are requesting public comments, suggestions, and recommendations on the possible criteria and circumstances needed to warrant a new base period, and, importantly, the documentation that would be required to qualify, particularly relative to and differentiating it from an adjustment.

As stated earlier, we are inviting comments, suggestions, and recommendations for regulatory and other policy changes to the TEFRA adjustment process. We also are interested in feedback on whether or not there should be standardization in the supporting documentation (such as electronic workbooks) as part of TEFRA adjustment requests and, if so, we invite commenters to provide specific examples.

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Proposed Change Related to CAH Payment for Ambulance Services

a. Background

Section 1834(l) of the Act sets forth the payment rules for ambulance services. Generally, payment to ambulance providers and suppliers for ambulance services are made under the Ambulance Fee Schedule. Section 205 of BIPA (Pub. L. 106–554) amended section 1834(l) of the Act by adding a paragraph (8), which, effective for services furnished on or after December 21, 2000, provided that the Secretary would pay the reasonable costs incurred in furnishing ambulance services if such services are furnished by a CAH (as defined in section 1861(mm)(1) of the Act), or by an entity that is owned and operated by a CAH, but only if the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of the CAH. Regulations implementing section 1834(l)(8) of the Act are set forth at 42 CFR 413.70(b)(5). For purposes of this discussion, the term ''provider'' of ambulance services means all Medicare-participating providers that submit claims under Medicare for ambulance services (for example, hospitals, CAHs, skilled nursing facilities (SNFs), and home health agencies (HHAs)), and the term ''supplier'' of ambulance services means an entity that provides ambulance services and that is independent of any Medicare-participating or non-Medicare-participating provider. The terms ''supplier'' and ''provider of services'' are defined in sections 1861(d) and (u) of the Act, respectively, and the term ''provider or supplier of ambulance services'' appears in section 1834(l)(8) of the Act.

Section 3128(a) of the Affordable Care Act (Pub. L. 111–148) amended section 1834(l)(8) of the Act by specifying that payment for the reasonable costs incurred by a CAH or by an entity that is owned and operated by a CAH in furnishing ambulance services would be at ''101 percent'' of the reasonable costs incurred in furnishing such services. As such, section 3128(a) of the Affordable Care Act increased payment for ambulance services furnished by CAHs or entities owned and operated by CAHs to 101 percent of the reasonable costs, subject to the requirements outlined in section 1834(l)(8) of the Act, effective for cost reporting periods beginning on or after January 1, 2004. We amended § 413.70(b)(5)(i) in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50361) to conform to the statute, as amended.

More recently, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51729), to ensure consistency between the regulations and statute, we revised § 413.70(b)(5)(i) by adding a new paragraph (C) to state that, effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or by a CAH-owned and operated entity is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. If there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH. Therefore, a CAH is paid 101 percent of the reasonable costs for its ambulance services only if there is no other provider or supplier of ambulance

services within a 35-mile drive of the CAH. If there is another provider or supplier of ambulance services located within a 35-mile drive of the CAH, the CAH is paid for its ambulance services using the Ambulance Fee Schedule.

b. Proposed Change

As indicated above and in accordance with statutory language at section 1834(l)(8) of the Act, § 413.70(b)(5)(i)(C) currently states in relevant part that payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. It has been brought to our attention that there may be instances where a provider or supplier of ambulance services that is not owned or operated by the CAH is located within a 35-mile drive of the CAH, but that provider or supplier of ambulance services is not legally authorized to furnish ambulance services to transport individuals either to or from the CAH. For example, consider the scenario where an ambulance supplier is located within a 35-mile drive of a CAH, but in a different State, and the ambulance supplier is not legally authorized (for example, the supplier of ambulance services does not have the appropriate State licensure) to furnish ambulance services in the State in which the CAH is located. Under this scenario, § 413.70(b)(5)(i)(C) requires that the CAH be paid for its ambulance services using the Ambulance Fee Schedule, even though the out-of-state ambulance supplier cannot actually furnish ambulance services to transport individuals either to or from the CAH. We believe this outcome is not consistent with the intent of the Medicare Rural Hospital Flexibility Program, which is to provide access to care to individuals living in remote and rural areas. A CAH may provide crucial health care services to individuals living in a remote and rural area; however, if transport services to that CAH are limited due to lack of ambulance services, health care services available to individuals living in the CAH's service area may also be limited. A lack of ambulance services within the CAH's service area could limit access to care for individuals living in these remote and rural areas, particularly in emergency situations and when individuals have no other mode of transportation due to hazardous traveling conditions. In general, payment for ambulance services based on 101 percent of the reasonable costs is higher than payment made under the Ambulance Fee Schedule. This higher payment is intended to provide CAHs with sufficient payment to sustain their own ambulance services when no other ambulance services are available in their service area. If a CAH does not receive reasonable cost-based payments for its ambulance services because there is another provider or supplier of ambulance services within a 35-mile drive of the CAH, even if that provider or supplier is not legally authorized to transport individuals either to or from the CAH, the CAH may be unable to support the costs of providing ambulance services in its service area.

Therefore, we are proposing to address this ''gap'' in the current regulation at § 413.70(b)(5)(i)(C) by revising our interpretation of the requirement in section 1834(l)(8)(B) of the Act that the CAH or the entity owned and operated by the CAH be the only provider or supplier of ambulance services that is located within a 35-mile drive of such a CAH, to exclude consideration of ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals either to or from the CAH. Specifically, we would interpret section 1834(l)(8)(B) of the Act to mean that the CAH or the CAH-owned and operated entity must be the only provider or supplier of ambulance services within a 35-mile drive of the CAH that is legally authorized to furnish ambulance services to individuals transported to or from the CAH. We believe this is a reasonable reading of the statutory language because it retains the requirement that the CAH or the CAH-owned and operated entity be the only provider or supplier of ambulance services within a 35-mile drive of the CAH that is available to transport individuals either to or from the CAH. We are proposing to revise § 413.70(b)(5)(i) of the regulations to reflect this revised interpretation by adding a new paragraph (D) to state that, effective for cost reporting periods beginning on or after October 1, 2019, payment for ambulance services furnished by a CAH or by an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals either to or from the CAH. Consistent with the existing policy under § 413.70(b)(5)(i)(C), if there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH. We also are proposing a conforming change to § 413.70(b)(5)(i)(C) to make that existing provision effective only through September 30, 2019.

As stated earlier in this discussion, if a CAH does not receive reasonable cost-based payments for its ambulance services, which in general provide higher payment compared to the Ambulance Fee Schedule, the CAH may be unable to support the costs of providing ambulance services in its service area. As such, we believe that our proposed change to allow for payment based on 101 percent of the reasonable costs of the CAH or the CAH-owned and operated entity in furnishing ambulance services, in a situation where there is another provider or supplier of ambulance services located within a 35-mile drive of the CAH that is not legally authorized to transport individuals either to or from the CAH, would improve access to care in remote and rural areas, particularly in situations where an individual is experiencing an emergency and can only receive the necessary services through ambulance transport to or from the CAH or in situations where no other mode of transportation is advisable. Furthermore, we believe our proposal is consistent with the original purpose of section 1834(l)(8) of the Act, which was to help ensure that areas served by CAHs would have adequate access to ambulance services.

3. Frontier Community Health Integration Project (FCHIP) Demonstration

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act, authorizes a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to

Medicare beneficiaries. The demonstration is titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and is commonly known as the Frontier Community Health Integration Project (FCHIP) demonstration.

The authorizing statute states the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is an MRHFP grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the State are counties that have 6 or less residents per square mile.

The authorizing statute stipulates several other requirements for the demonstration. Section 123(d)(2)(B) of Public Law 110–275, as amended, limits participation in the demonstration to eligible entities in not more than 4 States. Section 123(f)(1) of Public Law 110–275 requires the demonstration project to be conducted for a 3-year period. In addition, section 123(g)(1)(B) of Public Law 110–275 requires that the demonstration be budget neutral. Specifically, this provision states that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 states that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration.

In January 2014, CMS released a request for applications (RFA) for the FCHIP demonstration. Using 2013 data from the U.S. Census Bureau, CMS identified Alaska, Montana, Nevada, North Dakota, and Wyoming as meeting the statutory eligibility requirement for participation in the demonstration. The RFA solicited CAHs in these five States to participate in the demonstration, stating that participation would be limited to CAHs in four of the States. To apply, CAHs were required to meet the eligibility requirements in the authorizing legislation, and, in addition, to describe a proposal to enhance health-related services that would complement those currently provided by the CAH and better serve the community's needs. In addition, in the RFA, CMS interpreted the eligible entity definition in the statute as meaning a CAH that receives funding through the MHRFP. The RFA identified four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services, respectively. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Ten CAHs were selected for participation in the demonstration, which started on August 1, 2016. These CAHs are located in Montana, Nevada, and North Dakota, and they are participating in three of the four interventions identified in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517). Eight CAHs are participating in the telehealth intervention, three CAHs are participating in the skilled nursing facility/nursing facility bed intervention, and two CAHs are participating in the ambulance services intervention. Each CAH is allowed to participate in more than one of the interventions. None of the selected CAHs are participants in the home health intervention, which was the fourth intervention included in the RFA.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), we finalized a policy to address the budget neutrality requirement for the demonstration. As explained in the FY 2019 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration and uncertainty associated with projected Medicare utilization and costs, we adopted a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for these CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. Because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration were not implemented, we will comply with the budget neutrality requirement by reducing payments to all CAHs, not just those participating in the demonstration. We stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Based on actuarial analysis using cost report settlements for FYs 2013 and 2014, the demonstration is projected to satisfy the budget neutrality requirement and likely yield a total net savings. As we estimated for the FY 2019 IPPS/LTCH PPS final rule, for this FY 2020 IPPS/LTCH PPS proposed rule, we estimate that the total impact of the payment recoupment will be no greater than 0.03 percent of CAHs' total Medicare payments within one fiscal year (that is, Medicare Part A and Part B). The final budget neutrality estimates for the FCHIP demonstration will be based on the demonstration period, which is August 1, 2016 through July 31, 2019.

The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. As stated in the FY 2019 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of 3 cost reporting years, beginning in CY 2020.

The 3-year period for recoupment will allow for a reasonable timeframe for the payment reduction and to minimize any impact on CAHs' operations. Based on the currently available data and because any reduction to CAH payments in order to recoup excess costs under the demonstration will not begin until CY 2020, this policy will likely have no impact for any national payment system for FY 2020.

VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2020

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act (''subclause II'' LTCHs) also provided an alternative definition of LTCHs. However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals''), to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS. For more information on these provisions, we refer readers to 82 FR 38299.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of

2018, Public Law 115–123, which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-percent threshold policy under 42 CFR 412.538.

In this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing revisions to our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b–1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act), or section 3201 of the Patient Protection and Affordable Care Act (Pub. L. 111–148 (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for services furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FY 2016 or FY 2017) are considered to be site neutral payment rate payments.

B. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2020

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA (Pub. L. 106–113).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. There are currently 761 MS–DRG

groupings. For FY 2020, there would be 761 MS–DRG groupings based on the proposed changes, as discussed in section II.F. of the preamble of this FY 2020 IPPS/LTCH PPS proposed rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In this section of the proposed rule, we provide a general summary of our existing methodology for determining the proposed FY 2020 MS–LTC–DRG relative weights under the LTCH PPS.

In this FY 2020 IPPS/LTCH PPS proposed rule, in general, for FY 2020, we are proposing to continue to use our existing methodology to determine the proposed MS–LTC–DRG relative weights (as discussed in greater detail in section VII.B.3. of the preamble of this proposed rule). As we established when we implemented the dual rate LTCH PPS payment structure codified under § 412.522, which began in FY 2016, we are proposing that the annual recalibration of the MS–LTC–DRG relative weights are determined: (1) Using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate had been in effect at the time of discharge when claims data from time periods before the dual rate LTCH PPS payment structure applies are used to calculate the relative weights; and (2) using only data from available LTCH PPS claims that qualify for payment under the new LTCH PPS standard Federal payment rate when claims data from time periods after the dual rate LTCH PPS payment structure applies are used to calculate the relative weights (80 FR 49624). That is, under our current methodology, our MS–LTC–DRG relative weight calculations do not use data from cases paid at the site neutral payment rate under § 412.522(c)(1) or data from cases that would have been paid at the site neutral payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of that discharge. For the remainder of this discussion, we use the phrase ''applicable LTCH cases'' or ''applicable LTCH data'' when referring to the resulting claims data set used to calculate the relative weights (as described later in greater detail in section VII.B.3.c. of the preamble of this proposed rule). In addition, in this FY 2020 IPPS/LTCH PPS proposed rule, for FY 2020, we are proposing to continue to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS–LTC–DRG relative weight calculations for the reasons discussed in section VII.B.3.c. of the preamble of this proposed rule.

Furthermore, for FY 2020, in using data from applicable LTCH cases to establish MS–LTC–DRG relative weights, we are proposing to continue to establish low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases) using our quintile methodology in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we grouped all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we account for adjustments made to LTCH PPS standard Federal payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG), and we make adjustments to account for nonmonotonically increasing weights, when necessary. The methodology is premised on more severe cases under the MS–LTC–DRG system requiring greater expenditure of medical care resources and higher average charges such that, in the severity levels within a base MS–LTC–DRG, the relative weights should increase monotonically with severity from the lowest to highest severity level. (We discuss each of these components of our MS–LTC–DRG relative weight methodology in greater detail in section VII.B.3.g. of the preamble of this proposed rule.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs), or minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Currently, for claims submitted using version ASC X12 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in Subparts I through S of Part 162. Among other requirements, on or after January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent

encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.F.1. of the preamble of this final rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2020

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2019, through September 30, 2020 (FY 2020), consistent with the proposed changes to specific MS–DRG classifications presented in section II.F. of the preamble of this proposed rule. Accordingly, the proposed MS–LTC–DRGs for FY 2020 presented in this proposed rule are the same as the proposed MS–DRGs that are being used under the IPPS for FY 2020. In addition, because the MS–LTC–DRGs for FY 2020 are the same as the proposed MS–DRGs for FY 2020, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed GROUPER Version 37 as discussed in section II.F. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–10–CM/PCS coding system, also would be applicable under the LTCH PPS for FY 2020.

3. Development of the Proposed FY 2020 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. In order to make these annual adjustments under the dual rate LTCH PPS payment structure, beginning with FY 2016, we recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases (80 FR 49614 through 49617). Under this policy, the resulting MS–LTC–DRG relative weights would continue to be used to adjust the LTCH PPS standard Federal payment rate when calculating the payment for LTCH PPS standard Federal payment rate cases.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity resulting from the adoption of the MS–LTC–DRGs, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal

payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

b. Development of the Proposed MS–LTC–DRG Relative Weights for FY 2020

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41521 through 41529), we presented our policies for the development of the MS–LTC–DRG relative weights for FY 2019.

In this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to continue to use our current methodology to determine the proposed MS–LTC–DRG relative weights for FY 2020, including the continued application of established policies related to: The hospital-specific relative value methodology, the treatment of severity levels in the proposed MS–LTC–DRGs, proposed low-volume and no-volume MS–LTC–DRGs, proposed adjustments for nonmonotonicity, the steps for calculating the proposed MS–LTC–DRG relative weights with a proposed budget neutrality factor, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate (or, for discharges occurring prior to the implementation of the dual rate LTCH PPS payment structure, would have met the criteria for exclusion had those criteria been in effect at the time of the discharge)).

In this section, we present our proposed application of our existing methodology for determining the proposed MS–LTC–DRG relative weights for FY 2020, and we discuss the effects of our proposals concerning the data used to determine the proposed FY 2020 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41522), we now generally provide the low-volume quintiles and no-volume crosswalk data previously published in Tables 13A and 13B for each annual proposed and final rule as one of our supplemental IPPS/LTCH PPS related data files that are made available for public use via the internet on the CMS website for the respective rule and fiscal year (that is, FY 2019 and subsequent fiscal years) at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of IPPS Table 11 and to make it easier for the public to navigate and find the relevant data and information used for the development of proposed and final payment rates or factors for the applicable payment year while continuing to furnish the same information the tables provided in previous fiscal years. We refer readers to the CMS website for the low-volume quintiles and no-volume crosswalk data previously furnished via Tables 13A and 13B.

c. Data

For this FY 2020 IPPS/LTCH PPS proposed rule, consistent with our proposals regarding the calculation of the proposed MS–LTC–DRG relative weights for FY 2020, we obtained total charges from FY 2018 Medicare LTCH claims data from the December 2018 update of the FY 2018 MedPAR file, which are the best available data at this time, and we are proposing to use Version 37 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we are proposing that if more recent data become available, we would use those data and the finalized Version 37 of the GROUPER in establishing the FY 2020 MS–LTC–DRG relative weights in the final rule. To calculate the proposed FY 2020 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are proposing to continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we began by first evaluating the LTCH claims data in the December 2018 update of the FY 2018 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. We identified the FY 2018 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945 and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or
- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2017 MedPAR file that reported ICD–10–PCS procedure code 5A1955Z were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion.

We note that, for purposes of developing the proposed FY 2020 MS–LTC–DRG relative weights using our current methodology, we are not making any proposals for exceptions regarding the identification of cases that would have been excluded from the site neutral payment rate under the statutory provisions that provided for temporary exception from the site neutral payment rate under the LTCH PPS for certain severe wound care discharges from certain LTCHs or for certain spinal cord specialty hospitals provided by sections 15009 and 15010 of Public Law 114–255, respectively, had our implementation of that law and the dual rate LTCH PPS payment structure been in effect at the time of the discharge. At this time, it is uncertain how many LTCHs and how many cases in the claims data we are using for this proposed rule meet the criteria to be excluded from the site neutral payment rate under those exceptions (or would have met the criteria for exclusion had the dual rate LTCH PPS payment structure been in effect at the time of the discharge). Therefore, for the remainder of this section, when we refer to LTCH claims only from cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had the applicable statutes been in effect at the time of the discharge), such data do not include any discharges that would have been paid

based on the LTCH PPS standard Federal payment rate under the provisions of sections 15009 and 15010 of Public Law 114–255, had the exception been in effect at the time of the discharge.

Furthermore, consistent with our historical methodology, we are excluding any claims in the resulting data set that were submitted by LTCHs that were all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we are excluding any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files. The claims that remained after these three trims (that is, the applicable LTCH data) were then used to calculate the proposed MS–LTC–DRG relative weights for FY 2020.

In summary, in general, we identified the claims data used in the development of the proposed FY 2020 MS–LTC–DRG relative weights in this proposed rule, as we are proposing, by trimming claims data that were paid the site neutral payment rate (or would have been paid the site neutral payment rate had the dual payment rate structure been in effect, except for discharges which would have been excluded from the site neutral payment under the temporary exception for certain severe wound care discharges from certain LTCHs and under the temporary exception for certain spinal cord specialty hospitals), as well as the claims data of 8 all-inclusive rate providers reported in the December 2018 update of the FY 2018 MedPAR file and any Medicare Advantage claims data. (We note that, there were no data from any LTCHs that are paid in accordance with a demonstration project reported in the December 2018 update of the FY 2018 MedPAR file. However, had there been we would trim the claims data from those LTCHs as well, in accordance with our established policy.) We are proposing to use the remaining data (that is, the applicable LTCH data) to calculate the proposed relative weights for FY 2020.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the proposed MS–LTC–DRG relative weights for FY 2020. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we are proposing to reduce the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs).

In accordance with our established methodology, for FY 2020, we are proposing to continue to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.B.3.g. (Step 3) of the preamble of this proposed rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the Proposed MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section of the proposed rule) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail below). For FY 2020, we are proposing to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the proposed FY 2020 MS–LTC–DRG relative weights.

In determining the proposed FY 2020 MS–LTC–DRG relative weights, when necessary, as is our longstanding practice, we are proposing to make adjustments to account for nonmonotonicity, as discussed in

greater detail later in Step 6 of section VII.B.3.g. of the preamble of this proposed rule. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Proposed Low-Volume MS–LTC–DRGs

In order to account for proposed MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we are proposing to continue to employ the quintile methodology for proposed low-volume MS–LTC–DRGs, such that we group the proposed ''low-volume MS–LTC–DRGs'' (that is, proposed MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148).) In cases where the initial assignment of a low-volume proposed MS–LTC–DRG to a quintile results in nonmonotonicity within a base-DRG, we are proposing to make adjustments to the resulting low-volume proposed MS–LTC–DRGs to preserve monotonicity, as discussed in detail in section VII.B.3.g. (Step 6) of the preamble of this proposed rule.

In this proposed rule, based on the best available data (that is, the December 2018 update of the FY 2018 MedPAR files), we identified 259 proposed MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of proposed MS–LTC–DRGs was then divided into 1 of the 5 low-volume quintiles, each containing at least proposed 51 MS–LTC–DRGs (259/5 = 51 with a remainder of 4). We assigned the proposed low-volume MS–LTC–DRGs to specific proposed low-volume quintiles by sorting the proposed low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this proposed rule, the number of proposed MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5 and, therefore, we are proposing to employ our historical methodology for determining which of the proposed low-volume quintiles would contain the additional proposed low-volume MS–LTC–DRG. Specifically for this proposed rule, after organizing the proposed MS–LTC–DRGs by ascending order by average charge, we assigned the first 52 (1st through 52nd) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. Because the average charge of the 52nd proposed low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 51st proposed low-volume MS–LTC–DRG (assigned to Quintile 1) than to the average charge of the 53rd proposed low-volume MS–LTC–DRG (assigned to Quintile 2), we assigned it to Quintile 1 (such that Quintile 1 contains 52 proposed low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). The 51 proposed MS–LTC–DRGs with the highest average charge were assigned into Quintile 5. This resulted in 4 of the 5 proposed low-volume quintiles containing 52 proposed MS–LTC–DRGs (Quintiles 1 through 4) and 1 proposed low-volume quintile containing 51 proposed MS–LTC–DRGs (Quintile 5). As discussed earlier, for this proposed rule, we are providing the list of the composition of the proposed low-volume quintiles for proposed low-volume MS–LTC–DRGs for FY 2020 in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

In order to determine the proposed FY 2020 relative weights for the proposed low-volume MS–LTC–DRGs, consistent with our historical practice, we are proposing to use the five low-volume quintiles described previously. We determined a proposed relative weight and (geometric) average length of stay for each of the five proposed low-volume quintiles using the methodology described in section VII.B.3.g. of the preamble of this proposed rule. We are proposing to assign the same proposed relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases will vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to proposed low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the Proposed FY 2020 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to continue to use our current methodology to determine the proposed FY 2020 MS–LTC–DRG relative weights.

In summary, to determine the proposed FY 2020 MS–LTC–DRG relative weights, we are proposing to group applicable LTCH cases to the appropriate proposed MS–LTC–DRG, while taking into account the proposed low-volume quintiles (as described above) and cross-walked proposed no-volume MS–LTC–DRGs (as described later in this section). After establishing the appropriate proposed MS–LTC–DRG (or proposed low-volume quintile), we are proposing to calculate the proposed FY 2020 relative weights by first removing cases with a length of stay of 7 days or less and statistical outliers (Steps 1 and 2 below). Next, we are proposing to adjust the number of applicable LTCH cases in each proposed MS–LTC–DRG (or proposed low-volume quintile) for the effect of SSO cases (Step 3 below). After removing applicable LTCH cases with a length of stay of 7 days or less (Step 1 below) and statistical outliers (Step 2 below), which are the SSO-adjusted applicable LTCH cases and corresponding charges (Step 3 below), we are proposing to we calculate proposed ''relative adjusted weights'' for each proposed MS–LTC–DRG (or proposed low-volume quintile) using the HSRV method.

Step 1—Remove cases with a length of stay of 7 days or less.

The first step in our proposed calculation of the proposed FY 2020 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the FY 2020 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very

short stays. Therefore, consistent with our existing relative weight methodology, in determining the proposed FY 2020 MS–LTC–DRG relative weights, we are proposing to remove LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove statistical outliers.

The next step in our proposed calculation of the proposed FY 2020 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the proposed relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the proposed relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the proposed relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this proposed rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 3—Adjust charges for the effects of SSOs.

As the next step in the proposed calculation of the proposed FY 2020 MS–LTC–DRG relative weights, consistent with our historical approach, we are proposing to adjust each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the proposed FY 2020 MS–LTC–DRG relative weights would lower the proposed FY 2020 MS–LTC–DRG relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we are proposing to continue to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the proposed FY 2020 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed FY 2020 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we calculated a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each proposed MS–LTC–DRG, we calculated the proposed FY 2020 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the proposed MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent cases from Step 3 for each proposed MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent applicable LTCH cases from Step 3 for each proposed MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of proposed MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a proposed FY 2020 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the proposed MS–LTC–DRGs for which there were no claims in the December 2018 update of the FY 2018 MedPAR file and, therefore, for which no charge data was available for these proposed MS–LTC–DRGs. Because patients with a number of the diagnoses under these proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a proposed relative weight to each of the proposed no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' proposed MS–LTC–DRGs, ''error'' proposed MS–LTC–DRGs, and proposed MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this proposed rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

We are proposing to cross-walk each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG for which we calculated a proposed relative weight (determined in accordance with the methodology described above). Then, the ''no-volume'' proposed MS–LTC–DRG was assigned the same proposed relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was cross-walked

(as described in greater detail in this section of this proposed rule).

Of the 761 proposed MS–LTC–DRGs for FY 2020, we identified 320 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases (the number identified includes the 8 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed below). We are proposing to assign proposed relative weights to each of the 320 no-volume proposed MS–LTC–DRGs that contained trimmed applicable LTCH cases based on clinical similarity and relative costliness to 1 of the remaining 441 (761 − 320 = 441) proposed MS–LTC–DRGs for which we calculated proposed relative weights based on the trimmed applicable LTCH cases in the FY 2018 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' proposed MS–LTC–DRGs as the proposed MS–LTC–DRGs to which we cross-walked 1 of the 320 ''no-volume'' proposed MS–LTC–DRGs.) Then, we are generally proposing to assign the 320 no-volume proposed MS–LTC–DRGs the proposed relative weight of the cross-walked proposed MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

We cross-walked the no-volume proposed MS–LTC–DRG to a proposed MS–LTC–DRG for which we calculated proposed relative weights based on the December 2018 update of the FY 2018 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume proposed MS–LTC–DRGs in FY 2020, the proposed relative weights assigned based on the cross-walked proposed MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

We then assigned the proposed relative weight of the cross-walked proposed MS–LTC–DRG as the proposed relative weight for the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the cross-walked proposed MS–LTC–DRG) have the same proposed relative weight (and average length of stay) for FY 2020. We note that, if the cross-walked proposed MS–LTC–DRG had 25 applicable LTCH cases or more, its proposed relative weight (calculated using the methodology described in Steps 1 through 4 above) is assigned to the no-volume proposed MS–LTC–DRG as well. Similarly, if the proposed MS–LTC–DRG to which the no-volume proposed MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the proposed low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable proposed low-volume quintile to the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the cross-walked proposed MS–LTC–DRG) have the same proposed relative weight for FY 2020. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume proposed MS–LTC–DRG resulted, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing proposed relative weights.)

As discussed earlier, for this proposed rule, we are providing the list of the no-volume proposed MS–LTC–DRGs and the proposed MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked proposed MS–LTC–DRGs) for FY 2020 in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the proposed relative weights for the proposed FY 2020 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume proposed MS–LTC–DRGs crosswalk information for FY 2020 (which, as previously stated, we are providing in a supplemental data file posted via the internet on the CMS website for this proposed rule).

Example: There were no trimmed applicable LTCH cases in the FY 2018 MedPAR file that we are using for this proposed rule for proposed MS–LTC–DRG 061 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that proposed MS–LTC–DRG 070 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to proposed MS–LTC–DRG 061. Therefore, we assigned the same proposed relative weight (and average length of stay) of proposed MS–LTC–DRG 70 of 0.8909 for FY 2020 to proposed MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of proposed MS–LTC–DRGs with no volume will vary in the future. Consistent with our historical practice, we are proposing to use the most recent available claims data to identify the trimmed applicable LTCH cases from which we determine the relative weights in the final rule.

For FY 2020, consistent with our historical relative weight methodology, we are proposing to establish a proposed relative weight of 0.0000 for the following transplant proposed MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 008); Pancreas Transplant (MS–LTC–DRG 010); and Kidney Transplant (MS–LTC–DRG 652). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these eight proposed transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are proposing to establish a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an

MS–LTC–DRG according to the grouping logic.

Section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) extended the transitional blended payment rate for site neutral payment rate cases for an additional 2 years (that is, discharges occurring in cost reporting periods beginning in FYs 2018 and 2019 continued to be paid under the blended payment rate). Therefore, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), consistent with our practice in FYs 2016 through 2018, we established a relative weight for FY 2019 equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). As we discussed when we implemented the dual rate LTCH PPS payment structure, LTCH discharges that are grouped to these 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs do not meet the criteria for exclusion from the site neutral payment rate. As such, under the criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, there are no applicable LTCH cases to use in calculating a relative weight for the ''psychiatric and rehabilitation'' MS–LTC–DRGs. In other words, any LTCH PPS discharges grouped to any of the 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs would always be paid at the site neutral payment rate, and, therefore, those MS–LTC–DRGs would never include any LTCH cases that meet the criteria for exclusion from the site neutral payment rate. However, section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that would be paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017, which was extended to include FYs 2018 and 2019 under Public Law 115–123. (We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a detailed discussion of the extension of the transitional blended payment method provisions under Public Law 115–123 and our policies for FY 2019). Under the transitional blended payment method for site neutral payment rate cases, for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2018, and on or before September 30, 2019, site neutral payment rate cases are paid a blended payment rate, calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate. Because this transitional blended payment method for site neutral payment rate cases is applicable for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2018, and on or before September 30, 2019, some LTCHs' site neutral payment rate cases that are discharged during FY 2020 will be paid a blended payment rate.

Because the LTCH PPS standard Federal payment rate is based on the relative weight of the MS–LTC–DRG, in order to determine the transitional blended payment for site neutral payment rate cases grouped to one of the ''psychiatric or rehabilitation'' MS–LTC–DRGs in FY 2020, consistent with past practice, we are proposing to assign a relative weight to these MS–LTC–DRGs for FY 2020 that is the same as the FY 2019 relative weight (which is also the same as the FYs 2016 through 2019 relative weight). We believed that using the respective FY 2015 relative weight for each of the ''psychiatric or rehabilitation'' MS–LTC–DRGs results in appropriate payments for LTCH cases that are paid at the site neutral payment rate under the transition policy provided by the statute because there are no clinically similar MS–LTC–DRGs for which we were able to determine relative weights based on applicable LTCH cases in the December 2018 update of the FY 2018 MedPAR file data using the steps described above. Furthermore, we believed that it would be administratively burdensome and introduce unnecessary complexity to the MS–LTC–DRG relative weight calculation to use the LTCH discharges in the MedPAR file data to calculate a relative weight for those 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs to be used for the sole purposes of determining half of the transitional blended payment for site neutral payment rate cases during the transition period (80 FR 49631 through 49632) or payment for discharges from spinal cord specialty hospitals under § 412.522(b)(4).

In summary, for FY 2020, we are proposing to establish a relative weight (and average length of stay thresholds) equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs listed previously (that is, MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946). Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website, reflects this policy.

Step 6—Adjust the proposed FY 20120MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative

weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the proposed FY 2020 MS–LTC–DRG relative weights, consistent with our historical methodology, we are proposing to continue to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2020 MS–LTC–DRG relative weights in this proposed rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website.

Step 7— Calculate the proposed FY 2020 MS–LTC–DRG reclassification and recalibration budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). To achieve the budget neutrality requirement at § 412.517(b), under our established methodology, for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to update the MS–LTC–DRG classifications and relative weights for FY 2020 based on the most recent available LTCH data for applicable LTCH cases, and continue to apply a budget neutrality adjustment in determining the proposed FY 2020 MS–LTC–DRG relative weights.

In this FY 2020 IPPS/LTCH PPS proposed rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology.

To calculate the proposed normalization factor for FY 2020, we are proposing to group applicable LTCH cases using the proposed FY 2020 Version 37 GROUPER, and the recalibrated proposed FY 2020 MS–LTC–DRG relative weights to calculate the average case-mix index (CMI); we grouped the same applicable LTCH cases using the FY 2019 GROUPER Version 36 and MS–LTC–DRG relative weights and calculated the average CMI; and computed the ratio by dividing the average CMI for FY 2019 by the average CMI for proposed FY 2020. That ratio is the proposed normalization factor. Because the calculation of the proposed normalization factor involves the proposed relative weights for the proposed MS–LTC–DRGs that contained applicable LTCH cases to calculate the average CMIs, any low-volume proposed MS–LTC–DRGs are included in the calculation (and the proposed MS–LTC–DRGs with no applicable LTCH cases are not included in the calculation).

To calculate the proposed budget neutrality adjustment factor, we simulated estimated total FY 2020 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed FY 2020 normalized relative weights and proposed GROUPER Version 37; simulated estimated total FY 2020 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2019 MS–LTC–DRG relative weights and the FY 2019 GROUPER Version 36; and calculated the ratio of these estimated total payments by dividing the simulated estimated total LTCH PPS standard Federal payment rate payments using the FY 2019 MS–LTC–DRG relative weights and the GROUPER Version 36 by the simulated estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2020 MS–LTC–DRG relative weights and the proposed GROUPER Version 37. The resulting ratio is the proposed budget neutrality adjustment factor. The calculation of the proposed budget neutrality factor involves the proposed relative weights for the LTCH cases used in the payment simulation, which includes any cases grouped to low-volume proposed MS–LTC–DRGs or to proposed MS–LTC–DRGs with no applicable LTCH cases, and generally does not include payments for cases grouped to a proposed MS–LTC–DRG with no applicable LTCH cases. (Occasionally, a few LTCH cases (that is, those with a covered length of stay of 7 days or less), which are removed from the proposed relative weight calculation in step (2) that are grouped to a proposed MS–LTC–DRG with no applicable LTCH cases are included in the payment simulations used to calculate the proposed budget neutrality factor. However, the number and payment amount of such cases have a negligible impact on the proposed budget neutrality factor calculation).

In this proposed rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. Therefore, in this proposed rule, in the first step of our proposed MS–LTC–DRG budget neutrality methodology, for FY 2020, we are proposing to calculate and apply a proposed normalization factor to the recalibrated proposed relative weights (the result of Steps 1 through 6 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the proposed changes to the classification system. That is, the proposed normalization adjustment is intended to ensure that the recalibration of the proposed MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the proposed normalization factor for FY 2020 (the first step of our proposed budget neutrality methodology), we used the following three steps: (1.a.) Used the most recent available applicable LTCH cases from the most recent available data (that is, LTCH discharges from the

FY 2018 MedPAR file) and grouped them using the proposed FY 2020 GROUPER (that is, proposed Version 37 for FY 2020) and the recalibrated proposed FY 2020 MS–LTC–DRG relative weights (determined in Steps 1 through 6 above) to calculate the average case-mix index; (1.b.) grouped the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2019 GROUPER (Version 36) and FY 2019 MS–LTC–DRG relative weights and calculated the average case-mix index; and (1.c.) computed the ratio of these average case-mix indexes by dividing the average CMI for FY 2020 (determined in Step 1.a.) by the average case-mix index for FY 2019 (determined in Step 1.b.). As a result, in determining the proposed MS–LTC–DRG relative weights for FY 2020, each recalibrated proposed MS–LTC–DRG relative weight is multiplied by the proposed normalization factor of 1.271 (determined in Step 1.c.) in the first step of the proposed budget neutrality methodology, which produced ''normalized relative weights.''

In the second step of our proposed MS–LTC–DRG budget neutrality methodology, we calculated a second proposed budget neutrality factor consisting of the ratio of estimated aggregate FY 2020 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.a. mentioned previously) after reclassification and recalibration to estimated aggregate payments for FY 2020 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration (that is, the sum of all calculations under Step 1.b. mentioned previously).

That is, for this proposed rule, for FY 2020, under the second step of the proposed budget neutrality methodology, we are proposing to determine the proposed budget neutrality adjustment factor using the following three steps: (2.a.) Simulated estimated total FY 2020 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed normalized relative weights for FY 2020 and proposed GROUPER Version 37 (as described above); (2.b.) simulated estimated total FY 2020 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2019 GROUPER (Version 36) and the FY 2019 MS–LTC–DRG relative weights in Table 11 of the FY 2019 IPPS/LTCH PPS final rule available on the internet, as described in section VI. of the Addendum of that final rule; and (2.c.) calculated the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the proposed FY 2020 MS–LTC–DRG relative weights, each normalized proposed relative weight is then multiplied by a budget neutrality factor of 0.9971599 (the value determined in Step 2.c.) in the second step of the proposed budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the proposed FY 2020 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.271 and a budget neutrality factor of 0.9971599. Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2020.

C. Proposed Payment Adjustment for LTCH Discharges That Do Not Meet the Applicable Discharge Payment Percentage

Section 1886(m)(6)(C) of the Act, as added by section 1206 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), imposes several requirements related to an LTCH's discharge payment percentage. As defined by section 1886(m)(6)(C)(iv) of the Act, the term ''LTCH discharge payment percentage'' is a ratio, expressed as a percentage, of Medicare fee-for-service (FFS) discharges not paid the site neutral payment rate to total number of Medicare FFS discharges occurring during the cost reporting period. In other words, an LTCH's discharge payment percentage is the ratio of an LTCH's Medicare discharges that meet the criteria for exclusion from the site neutral payment rate (as described under § 412.522(a)), that is, discharges paid the LTCH PPS standard Federal payment rate, to an LTCH's total number of Medicare FFS discharges paid under the LTCH PPS during the cost reporting period. Section 1886(m)(6)(C)(ii)(I) of the Act, requires that, for cost reporting periods beginning on or after October 1, 2019, any LTCH with a discharge payment percentage for the cost reporting period that is not at least 50 percent be informed of such a fact; and section 1886(m)(6)(C)(ii)(II) of the Act requires that all of the LTCH's discharges in each successive cost reporting period be paid the payment amount that would apply under subsection (d) for the discharge if the hospital were a subsection (d) hospital, subject to the LTCH's compliance with the process for reinstatement provided for by section 1886(m)(6)(C)(iii) of the Act.

Section 1886(m)(6)(C)(i) of the Act requires that we provide notice to each LTCH of the LTCH's discharge payment percentage for LTCH cost reporting periods beginning during or after FY 2016. We implemented this requirement in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49613), and we have established subregulatory policies and timeframes by which we calculate and inform LTCHs of their discharge payment percentage. We note that, because the discharge payment percentage for a cost reporting period cannot be calculated until after the cost reporting period has ended, in order to ensure claims for the entire period are reflected, an LTCH is typically informed of the results of the calculation of the discharge payment percentage between 5 and 6 months after the end of the cost reporting period.

To implement the provisions of section 1886(m)(6)(C)(ii)(I) of the Act, as established by the amendments made by Public Law 113–67, we are proposing to continue to use our existing policy to calculate the discharge payment percentage and to inform LTCHs when their discharge payment percentage for the cost reporting period is not at least 50 percent. To implement the provisions of section 1886(m)(6)(C)(ii)(II) of the Act, as established by the amendments made by Public Law 113–67, we are proposing to establish the policy that an LTCH would become subject to a payment adjustment for all of its cost reporting periods beginning on or after October 1, 2019, and is notified that its calculated discharge payment percentage did not equal at least 50 percent. For example, if an LTCH has a calendar year cost reporting period, its first cost reporting period beginning on or after October 1, 2019 would be its January 1, 2020 through December 31, 2020 cost reporting period (that is, its FY 2020 cost reporting period). Because a cost reporting period must have ended and claims from the reporting period must be processed prior to the calculation of the discharge payment percentage, a hospital's discharge payment percentage for its FY 2020 cost reporting period cannot be calculated for approximately 6 months; that is, not completed until sometime during its FY 2021 cost reporting period. If the discharge payment percentage for its FY 2020 cost reporting period is not at least 50

percent (when calculated during its FY 2021 cost reporting period), under our proposal, the LTCH would become subject to a payment adjustment, applied to all discharges, for its FY 2022 cost reporting period (the first cost reporting period after its discharge payment percentage for a cost reporting period had been calculated to not have been at least 50 percent). We are proposing to codify the proposed implementation of these regulations establishing the policy to adjust payment to an LTCH for all discharges when the LTCH does not meet the discharge payment percentage after it is notified for cost reporting periods beginning on or after October 1, 2019, under proposed new § 412.522(d)(3).

As noted above, section 1886(m)(6)(C)(iii) of the Act, as established by the amendments made by Public Law 113–67, provides for the establishment of a reinstatement process whereby an LTCH can have the payment adjustment discontinued. To implement and maintain a reinstatement process as required by the statute, we are proposing to discontinue the payment adjustment for an LTCH's discharges as a result of its discharge payment percentage not equaling at least 50 percent beginning with the discharges occurring in the cost reporting period after the LTCH's discharge payment percentage is calculated to be at least 50 percent. For example, the LTCH with a calendar year cost reporting period that did not have a discharge payment percentage of at least 50 percent during its FY 2020 cost reporting period would be subject to the payment adjustment for its FY 2022 cost reporting period, as described above. However, if the discharge payment percentage for its FY 2021 cost reporting period equaled at least 50 percent, the calculation (and notification thereof) of such percentage would be made during FY 2022, and the payment adjustment would be discontinued beginning with discharges occurring at the start of its FY 2023 cost reporting period. We note that this proposed policy is based on cost reporting periods, is cyclical in nature, and, as such, an LTCH that has been reinstated would be subject to the payment adjustment again (in a future cost reporting period) if its discharge payment percentage is again calculated not to meet the required threshold. We are proposing to codify the proposed policy reinstatement process for LTCHs under the discharge payment percentage requirements in proposed new § 412.522(d)(5).

While we believe the proposed policy reinstatement process would satisfy the statutory requirement without further modification, because there could be unusual circumstances that result in a discharge payment percentage for a cost reporting period that may not be fully reflective of an LTCH's typical mix of site neutral and LTCH PPS standard Federal payment rate discharges (for example, patients require a shorter period of ventilation than was expected on admission), we also are proposing a special probationary reinstatement process, which is consistent with public comments we received during the FY 2016 rulemaking when the dual-rate payment system was implemented. While the public comments from the FY 2016 rulemaking cycle did not request that the special reinstatement process be probationary, we are concerned that, while there are unusual circumstances that may result in the discharge payment percentage for a cost reporting period not being fully reflective of an LTCH's typical mix of site neutral and LTCH PPS standard Federal payment rate discharges, if the special reinstatement process were not probationary, hospitals may be able to manipulate discharges or delay billing in such a way as to artificially inflate their discharge payment percentage for purposes of qualifying for the special reinstatement process. To alleviate these concerns, we are proposing that the special reinstatement process be probationary. Under this proposed special probationary reinstatement process, a probationary-cure period would allow an LTCH the opportunity to have the payment adjustment delayed during the applicable cost reporting period if, for the period of at least 5 consecutive months of the 6-month period immediately preceding the beginning of the cost reporting period during which the adjustment would apply (we note this time period is consistent with our current policy for the average length-of-stay determination), the discharge payment percentage is calculated to be at least 50 percent. Under such circumstances, the LTCH would not ultimately be subject to the payment adjustment for the cost reporting period during which the adjustment would apply—provided that the discharge payment percentage for that cost reporting period is at least 50 percent. If the discharge payment percentage for that cost reporting period is not at least 50 percent, the adjustment will be applied to the cost reporting period at settlement. For example, an LTCH with a calendar year cost reporting period that does not have a discharge payment percentage of at least 50 percent during its FY 2020 cost reporting period would be informed of this during its FY 2021 cost reporting period. The payment adjustment would then apply during its FY 2022 cost reporting period. However, if in the 6-month period immediately preceding the cost reporting period for which the payment adjustment would apply (July 1, 2021 through December 31, 2021), the LTCH achieved at least 5 consecutive months with a discharge payment percentage that is calculated to be at least 50 percent, application of the payment adjustment would be delayed during the FY 2022 cost reporting period (that is, the payment adjustment would not be applied to any discharges that occur during the FY 2022 cost reporting period). However, if the discharge payment percentage that is ultimately calculated for that LTCH's FY 2022 cost reporting period (the period for which the payment adjustment would have applied if the LTCH had not met the requirements during the probationary-cure period) is not at least 50 percent, the payment adjustment delay would be lifted, and the penalty would be applied to payments made for all of the discharges that occurred during the FY 2022 cost reporting period at settlement.

We are proposing to codify the policy for a special probationary reinstatement process under proposed new § 412.522(d)(6). We note that we expect to issue subregulatory guidance to describe the specific procedures for implementing this proposed probationary-cure period, if the policy is finalized. However, we are inviting public comments on suggestions regarding the specific process to be used, including whether the process should mirror the existing process used by LTCHs for the greater than 25-day average length-of-stay requirements.

Section 1886(m)(6)(C)(ii) of the Act specifies that, subject to the process for reinstatement, when the requisite discharge patient percentage threshold is not met, all of the LTCH's discharges in each successive cost reporting period will be paid the payment amount that would apply under subsection (d) for the discharge if the hospital were a subsection (d) hospital. We note that ''subsection (d)'' as it is referred to under section 1886(d) of the Act refers to IPPS hospitals. For purposes of implementing the payment adjustment provisions of section 1886(m)(6)(C)(ii) of the Act, as established by the amendments of Public Law 113–67, we are proposing to establish the policy at proposed new § 412.522(d)(4) that, for cost reporting periods beginning on or after October 1, 2019, under this payment adjustment, the LTCH would receive payment for all discharges in the

cost reporting periods beginning after the LTCH is informed that its calculated discharge payment percent is not at least 50 percent at the amount comparable to the IPPS amount determined under §§ 412.529(d)(4)(i)(A) and (ii), with an additional payment for high-cost outlier cases that would be based on the IPPS fixed-loss amount in effect at the time of the LTCH discharge. We note that the amount comparable to the IPPS amount determined under §§ 412.529(d)(4)(i)(A) and (ii) is the basis of the IPPS comparable *per diem* amount (for which the *per diem* is calculated in accordance with the provisions of §§ 412.529(d)(4)(i)(B) and (C)) that are also used to calculate payments under the SSO policy at § 412.529(c)(4) and site neutral payment rate payments at § 412.522(c).

D. Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the LTCH PPS for FY 2020

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and 412.535. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal payment rate for FY 2020, that is, effective for LTCH discharges occurring on or after October 1, 2019 through September 30, 2020. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at § 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate (FYs 2003 through 2015)/LTCH PPS standard Federal payment rate (FY 2016 through present) as implemented under § 412.523(c)(3), we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (69 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773); FY 2013 IPPS/LTCH PPS final rule (77 FR 53479 through 53481); FY 2014 IPPS/LTCH PPS final rule (78 FR 50760 through 50765); FY 2015 IPPS/LTCH PPS final rule (79 FR 50176 through 50180); FY 2016 IPPS/LTCH PPS final rule (80 FR 49634 through 49637); FY 2017 IPPS/LTCH PPS final rule (81 FR 57296 through 57310); the FY 2018 IPPS/LTCH PPS final rule (82 FR 58536 through 58547); and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41530 through 41537).

In this FY 2020 IPPS/LTCH PPS proposed rule, we present our proposals related to the annual update to the LTCH PPS standard Federal payment rate for FY 2020.

The proposed update to the LTCH PPS standard Federal payment rate for FY 2020 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2020 are discussed below, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2020 as required by the statute (as discussed in section VII.D.2.c. of the preamble of this proposed rule). We also are proposing to make an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2020 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4) (as discussed in section V.B. of the Addendum to this proposed rule).

In addition, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41532 through 41537), we eliminated the 25-percent threshold policy in a budget neutral manner. The budget neutrality requirements are codified in the regulations at § 412.523(d)(6). Under these regulations, a temporary, one-time factor is applied to the standard Federal payment rate in FY 2019 and FY 2020, and a permanent, one-time factor in FY 2021. These factors as established in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41536) are:

- For FY 2019, a temporary, one-time factor of 0.990884;
- For FY 2020, a temporary, one-time factor of 0.990741; and
- For FY 2021 and subsequent years, a permanent, one-time factor of 0.991249.

Therefore, in determining the proposed FY 2020 LTCH PPS standard Federal payment rate, we are proposing to:

(1) Remove the temporary, one-time factor of 0.990884 for the estimated cost of the elimination of the 25-percent threshold policy in FY 2019 by applying a factor of (1/0.990884); and

(2) Apply a temporary, one-time factor of 0.990741 for the estimated cost of the elimination of the 25-percent threshold policy in FY 2020.

Equivalently, in determining the proposed FY 2020 LTCH PPS standard Federal payment rate, we are proposing to apply a temporary, one-time factor of 0.999856 ($1/0.990884 \times 0.990741$) to the FY 2019 LTCH PPS standard Federal payment rate. The proposed FY 2020 LTCH PPS standard Federal payment rate shown in Table 1E in section VI. of the Addendum to this proposed rule reflects this adjustment.

2. Proposed FY 2020 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2013-based LTCH market basket for use under the LTCH PPS beginning in FY 2017 (81 FR 57100 through 57102). For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2013-based LTCH market basket, we refer readers to section VII.D. of the preamble of the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 25153 through 25167 and 81 FR 57086 through 57099, respectively).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to

any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Proposed Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2020

CMS has used an estimated market basket increase to update the LTCH PPS. As noted above, we adopted the 2013-based LTCH market basket for use under the LTCH PPS beginning in FY 2017. The 2013-based LTCH market basket is based solely on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. (For additional details on the development of the 2013-based LTCH market basket, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57099).) We continue to believe that the 2013-based LTCH market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted its use in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57100). Therefore, in this proposed rule, we are proposing to use the 2013-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2020.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A). Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, ''the multifactor productivity (MFP) adjustment''). Clause (ii) of section 1886(m)(3)(A) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act; therefore, it is not applicable for FY 2020.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Proposed Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage point reduction to any update under § 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (§ 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at § 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this proposed rule.)

d. Proposed Annual Market Basket Update Under the LTCH PPS for FY 2020

Consistent with our historical practice and our proposal, we estimate the market basket increase and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's fourth quarter 2018 forecast, the FY 2020 full market basket estimate for the LTCH PPS using the 2013-based LTCH market basket is 3.2 percent. The current estimate of the MFP adjustment for FY 2020 based on IGI's fourth quarter 2018 forecast is 0.5 percent.

For FY 2020, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment (''the MFP adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the full estimated FY 2020 market basket increase by the proposed FY 2020 MFP adjustment. To determine the proposed market basket increase for LTCHs for FY 2020, as reduced by the proposed MFP adjustment, consistent with our established methodology, we are subtracting the proposed FY 2020 MFP adjustment from the estimated FY 2020 market basket increase. (We note that sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act required an additional reduction each year only for FYs 2010 through 2019.) (For additional details on our established methodology for adjusting the market basket increase by the MFP adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2020, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, the proposed 3.2 percent update to the LTCH PPS standard Federal payment rate for FY 2020 will be reduced by the proposed 0.5 percentage point MFP adjustment as required under section 1886(m)(3)(A)(i) of the Act and the additional 2.0 percentage points reduction required by section 1886(m)(5) of the Act.

In this FY 2020 IPPS/LTCH PPS proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2020 full market basket estimate of 3.2 percent (based on IGI's

fourth quarter 2018 forecast of the 2013-based LTCH market basket) by the proposed FY 2020 MFP adjustment of 0.5 percentage point (based on IGI's fourth quarter 2018 forecast). Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to establish an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2020 of 2.7 percent (that is, the most recent estimate of the proposed LTCH PPS market basket increase of 3.2 percent, less the proposed MFP adjustment of 0.5 percentage point). Accordingly, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (xvi), which would specify that the LTCH PPS standard Federal payment rate for FY 2020 is the LTCH PPS standard Federal payment rate for the previous LTCH PPS payment year updated by 2.7 percent, and as further adjusted, as appropriate, as described in § 412.523(d) (including the application of the proposed adjustment factor for the cost of the elimination of the 25-percent threshold policy under § 412.523(d)(6) discussed above). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under proposed § 412.523(c)(3)(xvi) in conjunction with § 412.523(c)(4), we are proposing to further reduce the proposed annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.7 percent (that is, 2.7 percent minus 2.0 percentage points) for FY 2020 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. Consistent with our historical practice, we are proposing to use a more recent estimate of the market basket and the MFP adjustment in the final rule to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2020 under proposed § 412.523(c)(3)(xvi). (We note that, consistent with historical practice, we also are proposing to adjust the proposed FY 2020 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to this proposed rule).)

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In section VIII. of the preamble of this proposed rule, we are proposing changes to the following Medicare quality reporting systems:

- In section VIII.A., the Hospital IQR Program;
- In section VIII.B., the PCHQR Program; and
- In section VIII.C., the LTCH QRP.

In addition, in section VIII.D. of the preamble of this proposed rule, we are proposing changes to the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for eligible hospitals and critical access hospitals (CAHs).

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of the Hospital IQR Program

The Hospital IQR Program strives to put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high quality health care for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across the Department of Health and Human Services, we believe the Hospital IQR Program incentivizes hospitals to improve health care quality and value, while giving patients the tools and information needed to make the best decisions for them.

We seek to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of widely-agreed upon quality and cost measures. We have worked with relevant stakeholders to define measures in almost every care setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess clinical processes, patient safety and adverse events, patient experiences with care, care coordination, and clinical outcomes, as well as cost of care. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609) for the measures we have previously adopted for the Hospital IQR Program measure set for the FY 2022 payment determination and subsequent years.

b. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538) in which we summarized how the Hospital IQR Program maintains the technical measure specifications for quality measures and the subregulatory process for incorporation of nonsubstantive updates to the measure specifications to ensure that measures remain up-to-date. We are not proposing any changes to these policies in this proposed rule.

c. Public Display of Quality Measures

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41539) in which we stated the Hospital IQR Program's policy for public display of quality measures. We are not proposing any changes to these policies in this proposed rule.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513) for our finalized measure retention policy. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures. We are not proposing any changes to this policy in this proposed rule.

3. Removal Factors for Hospital IQR Program Measures

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal factors. We are not proposing any changes to

our policies regarding measure removal in this proposed rule.

4. Considerations in Expanding and Updating Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the previous considerations we have used to expand and update quality measures under the Hospital IQR Program. We also refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), in which we describe the Meaningful Measures Initiative,[409] our objectives under this new framework for quality measurement, and the quality topics that we have identified as high impact measurement areas that are relevant and meaningful to both patients and providers. Furthermore, in selecting measures for the Hospital IQR Program, we are mindful that measures adopted for the Hospital VBP Program must first have been adopted under the Hospital IQR Program and publicly reported on the *Hospital Compare* website for at least 1 year. We view the value-based purchasing programs, including the Hospital VBP Program, as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality health care for its beneficiaries. We are not proposing any changes to these policies in this proposed rule.

5. Proposed New Measures for the Hospital IQR Program Measure Set

In this proposed rule, we are proposing to: (1) Adopt two new quality measures beginning with the FY 2023 payment determination; and (2) expand the voluntary reporting status of the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (Hybrid HWR measure), and then require mandatory reporting of this measure beginning with the FY 2026 payment determination, as discussed in detail below.

a. Proposed Adoption of Two Opioid-Related eCQMs

In this proposed rule, we are proposing to add the following two opioid-related electronic clinical quality measures (eCQMs) to the Hospital IQR Program eCQM measure set, beginning with the CY 2021 reporting period/FY 2023 payment determination: (1) Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e); and (2) Hospital Harm—Opioid-Related Adverse Events eCQM.

We believe these opioid-related measures are valuable patient safety measures and are responsive to stakeholder feedback expressing support for eCQMs that focus on higher priority measurement areas and patient outcomes. While both measures are designed to reduce adverse events or harms associated with opioid use, the main focus of each measure's intent is different.

The Safe Use of Opioids—Concurrent Prescribing eCQM focuses on concurrent prescriptions of opioids and benzodiazepines at discharge, an area of high-risk prescribing. Implementation of the measure has the potential to reduce preventable mortality and costs of adverse events associated with prescription opioid use and could contribute to efforts to combat the current opioid epidemic, which is a high-priority focus area for measurement.

The Hospital Harm—Opioid-Related Adverse Events eCQM is designed to reduce adverse events associated with the administration of opioids in the hospital setting by assessing the administration of naloxone as an indicator of harm. Implementation of the measure can lead to safer patient care by incentivizing hospitals to track and improve their monitoring of patients who receive opioids during hospitalization.

Adopting these two opioid-related eCQMs would further diversify the eCQM measure set by addressing two additional Meaningful Measures quality priorities that are not currently addressed by the eCQM measure set: ''Promoting Effective Prevention and Treatment of Chronic Disease'' and ''Making Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Areas of ''Prevention and Treatment of Opioid and Substance Use Disorders'' and ''Preventable Healthcare Harm,'' respectively.

Additional details on each of the opioid-related eCQMs are presented below. We also refer readers to two related proposals in this proposed rule: (1) Section VIII.A.10.d.(1) through (4) of the preamble of this proposed rule for a discussion of proposed reporting and submission requirements for eCQMs through the CY 2022 reporting period/FY 2024 payment determination, including our proposal to require hospitals to report on the Safe Use of Opioids—Concurrent Prescribing eCQM as one of the four required eCQMs effective beginning with the CY 2022 reporting period/FY 2024 payment determination; and (2) section VIII.D.6.a. and b. of the preamble of this proposed rule for similar proposals to adopt these two opioid-related eCQMs in the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs).

(1) Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e)

(a) Background

Fatalities from unintentional opioid overdose have become an epidemic in the last 20 years, representing a major public health concern in the United States.[410] According to the Centers for Disease Control and Prevention (CDC), opioid overdose resulted in more than 42,000 deaths in 2016, and 40 percent of those deaths involved prescription opioids.[411] In addition, a recent retrospective study of claims data found that concurrent benzodiazepine and opioid use increased by 80 percent between 2001 and 2013 in a large sample of privately insured patients, and significantly contributed to the overall population risk of opioid overdose in the United States.[412]

Concurrent prescriptions of opioids or opioids and benzodiazepines place patients at a greater risk of unintentional overdose due to the increased risk of respiratory depression.[413] According to the National Institute on Drug Abuse, concurrent use of benzodiazepines with opioids was present in more than 30 percent of fatal overdoses, but many people continue to be prescribed both drugs simultaneously.[414] [415] Rates of fatal overdose are 10 times higher in

[409] Meaningful Measures web page: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[410] Rudd, R., Aleshire, N., Zibbell, J. & Gladden, R.M. (2016). Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014. *Morbidity and Mortality Weekly Report,* 64(50): 1378–82. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.*

[411] Centers for Disease Control and Prevention. *Drug Overdose Epidemic: Behind the Numbers.* Available at: *https://www.cdc.gov/drugoverdose/data/index.html.*

[412] Sun, E., Dixit, A., Humphreys, K., Darnall, B., Baker, L. & Mackey, S. (2017). Association Between Concurrent Use of Prescription Opioids and Benzodiazepines and Overdose: Retrospective Analysis. *BMJ,* 356: j760.

[413] Dowell, D., Haegerich, T. & Chou, R. (2016). CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. *Morbidity and Mortality Weekly Report: Recommendations and Reports,* 65. Available at: *http://www.cdc.gov/media/dpk/2016/dpk-opioid-prescription-guidelines.html.*

[414] National Institute on Drug Abuse. *Benzodiazepines and Opioids.* Available at: *https://www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids.*

[415] Sun, E., Dixit, A., Humphreys, K., Darnall, B., Baker, L. & Mackey, S. (2017). Association Between Concurrent Use of Prescription Opioids and Benzodiazepines and Overdose: Retrospective Analysis. *BMJ,* 356: j760.

patients who are co-dispensed opioid analgesics and benzodiazepines versus opioids alone.[416] Studies of multiple claims and prescription databases show that 5 to 15 percent of patients receive concurrent opioid prescriptions, and 5 to 20 percent of patients receive concurrent opioid and benzodiazepine prescriptions across various settings.[417] [418] [419] On average, the number of opioid overdose deaths involving benzodiazepines increased 14 percent each year from 2006 to 2011, whereas the number of opioid analgesic overdose deaths not involving benzodiazepines did not change significantly.[420] One study showed that reducing concurrent use of opioids and benzodiazepines could reduce the risk of opioid overdose-related emergency department (ED) and inpatient visits by 15 percent, and could have prevented an estimated 2,630 deaths related to opioid painkiller overdoses in 2015.[421] In the FY 2018 IPPS/LTCH PPS rulemaking (82 FR 20059 through 20060; 82 FR 38377 through 38378), we sought public comment on the potential future adoption of this measure.

(b) Overview of Measure

We believe that a measure that calculates the proportion of patients who were concurrently prescribed two or more opioids or opioids and benzodiazepines has the potential to reduce preventable mortality and the costs of adverse events associated with opioid use. Therefore, we are proposing to adopt the Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) beginning with the CY 2021 reporting period/FY 2023 payment determination. The Safe Use of Opioids—Concurrent Prescribing eCQM seeks to reduce preventable mortality and the costs of adverse events associated with opioid use by encouraging providers to identify patients who have concurrent prescriptions for opioids or opioids and benzodiazepines, and discouraging providers from prescribing these drugs concurrently whenever possible. The goal of the measure is to provide a patient-centric measure to help systems identify and monitor patients at risk, and ultimately to reduce the risk of harm to patients across the continuum of care. This measure also seeks to combat the opioid crisis, which has been declared a public health emergency,[422] and is recognized as a priority focus area for measurement by CMS and HHS. Specifically, by collecting and reporting concurrent prescribing rates with minimal lag time, this measure advances one of the key strategies prioritized by HHS in its five-point Opioid Strategy, which is to improve our understanding of the crisis through more timely, specific public health data collection and reporting.[423] In addition, under CMS' Meaningful Measures framework, the Safe Use of Opioids—Concurrent Prescribing eCQM addresses the quality priority of ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Prevention and Treatment of Opioid and Substance Use Disorders.'' [424]

The measure's concept is based on the *2016 CDC Guideline for Prescribing Opioids for Chronic Pain,* which recommends that clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible.[425] It is also in line with many state-issued and professional society guidelines on concurrent prescribing, which recommend that providers should avoid prescribing multiple opioids and opioids and benzodiazepines concurrently because it puts patients at high risk for respiratory depression, overdose, and death.[426]

In addition, stakeholders involved during development, including the project TEP and public commenters, stated that the measure was useful not only because it could promote adherence to recommended clinical guidelines, but also because capturing data on hospital-level prescribing practices could assist in identifying strategies to address the issue of concurrent prescriptions of opioids and benzodiazepines. Stakeholders also stated that the measure could reduce opioid-related mortality resulting from concurrent opioid prescriptions or opioid-benzodiazepine prescriptions, with minimal implementation costs.[427] Measure testing demonstrated that almost all of the data elements required to calculate and report the measure are collected as part of required clinical workflow protocols in structured fields within the EHR. The NQF Patient Safety Standing Committee did not raise any concerns on the feasibility of the measure during endorsement review.

[416] Dasgupta, N., Jonsson Funk, M., Proescholdbell, S., Hirsch, A., Ribisl, K.M. & Marshall, S. (2015). Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality. *Pain Medicine.* Available at: *http://onlinelibrary.wiley.com/doi/10.1111/pme.12907/abstract.*

[417] Liu, Y., Logan, J., Paulozzi, L., Zhang, K., Jones, C. (2013). Potential Misuse and Inappropriate Prescription Practices Involving Opioid Analgesics. *American Journal of Managed Care,* 19(8): 648–65.

[418] Mack, K., Zhang, K., Paulozzi, L. & Jones, C. (2015). Prescription Practices Involving Opioid Analgesics Among Americans with Medicaid, 2010. *Journal of Health Care for the Poor and Underserved,* 26(1): 182–98.

[419] Park, T., Saitz, R., Ganoczy, D., Ilgen, M.A. & Bohnert, A.S.B. (2015). Benzodiazepine Prescribing Patterns and Deaths from Drug Overdose Among U.S. Veterans Receiving Opioid Analgesics: Case-Cohort Study. *BMJ,* 350: h2698.

[420] Jones, C.M. & McAninch, J.K. (2015). Emergency Department Visits and Overdose Deaths from Combined Use of Opioids and Benzodiazepines. *American Journal of Preventive Medicine,* 49(4): 493–501.

[421] Sun, E., Dixit, A., Humphreys, K., Darnall, B., Baker, L. & Mackey, S. (2017). Association Between Concurrent Use of Prescription Opioids and Benzodiazepines and Overdose: Retrospective Analysis. *BMJ,* 356: j760.

[422] Office of the Assistant Secretary for Preparedness and Response (ASPR). Public Health Emergency Declarations. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/pages/default.aspx.*

[423] In April 2017, HHS identified the opioid crisis as a top priority and prioritized five specific strategies to combat the epidemic, including ''Better Data'' on the epidemic to improve our understanding of the crisis. HHS aims to strengthen public health data collection and reporting to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves. In its Strategy to Combat Opioid Abuse, Misuse, and Overdose, HHS sets forth a number of activities that can be taken by the Secretary and HHS agencies to advance its ''Better Data'' strategy, including the collection of data on opioid prescriptions, new drug patterns, and related harms, with minimal lag time. More information on HHS' Opioid Strategy is available at: *https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html.*

[424] The Safe Use of Opioids—Concurrent Prescribing measure also addresses the quality priority of ''Promoting Effective Communication and Coordination of Care'' through the Meaningful Measure area of ''Medication Management.'' More information on CMS' Meaningful Measures Initiative is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[425] Dowell, D., Haegerich, T. & Chou, R. (2016). CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. *Morbidity and Mortality Weekly Report: Recommendations and Reports,* 65. Available at: *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.*

[426] See, for example, American Academy of Emergency Medicine, *Emergency Department Opioid Prescribing Guidelines for the Treatment of Non-Cancer Related Pain* (available at: *https://www.deepdyve.com/lp/elsevier/american-academy-of-emergency-medicine-PlQtPNi8J4*) (recommending that clinicians should avoid prescribing opioid analgesics to patients currently taking sedative hypnotic medications or concurrent opioid analgesics); Washington State Agency Medical Directors' Group, *Interagency Guideline on Prescribing Opioids for Pain* (available at: *http://agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf*) (recommending that clinicians should avoid combining opioids with benzodiazepines, sedative-hypnotics or barbiturates when prescribing opioid for chronic noncancer pain).

[427] Gao, A., Bandyopadhyay, J., Barrett, K., Morales, N. & Tu, D. (2017). *Beta Testing Report on the Safe Use of Opioids—Concurrent Prescribing Electronic Clinical Quality Measure.* Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance Project (HHSM–500–2013–13011I, Task Order HHSM–500–T0003).

The Safe Use of Opioids—Concurrent Prescribing measure (MUC16–167) was included in the publicly available ''List of Measures Under Consideration for December 1, 2016.'' [428] The measure was reviewed by the NQF MAP in December 2016 and January 2017, which recommended that the measure be refined and resubmitted prior to rulemaking due to the importance of the opioid epidemic.[429] The MAP noted that there are instances where concurrent prescribing may be clinically appropriate, and that the measure could potentially cause unintentional consequences associated with withdrawal of medications. For more information on the concerns and considerations raised by the MAP related to this measure, we refer readers to the January 2017 NQF MAP Coordinating Committee Meeting Transcript.[430] In response to the MAP's recommendation, and as suggested by the project's TEP and expert work group, we explored single-condition exclusions, specifically for patients with sickle cell disease and those undergoing substance use therapy, and found that these instances comprised a very small portion of eligible cases captured by the numerator during testing.

After reviewing these testing results, expert opinions from clinicians recommended continuing to include patients for whom concurrent prescribing may be clinically necessary because experts stated that these populations are at highest risk of adverse drug events due to concurrent prescriptions and should continue to be monitored by clinicians throughout the continuum of care. In addition, there are currently no guidelines supporting exclusion of patients who may require concurrent prescriptions from the measure, other than cancer and palliative care; a broader set of evidence-based exclusions may increase the face validity of the measure, but there are currently no strong evidence-based indicators to support other exclusions beyond what is currently included in the measure that would continue to maintain the strength of the measure's evidence base.

To strengthen the measure's feasibility and usability, the measure was refined to address other feedback from the MAP such as: (1) Including only encounters for inpatient, ED, and hospital observation stays (rather than including encounters spanning inpatient and hospital outpatient settings); and (2) including only medications prescribed at discharge (rather than those spanning the duration of the encounter). An update on the measure was presented to the MAP on November 8, 2018.[431]

The NQF Patient Safety Standing Committee also recommended endorsement of the proposed measure in 2018, acknowledging that there is strong evidence for an association between increased use of multiple opioids, or opioids and benzodiazepines together, as well as increased risk of unintentional and fatal overdoses.[432] The committee agreed that this measure will likely reduce concurrent prescribing of opioid-opioid and opioid-benzodiazepine medications at discharge in inpatient and ED settings.[433] This measure was endorsed by the NQF in May 2018.[434]

Concurrent opioid or opioid-benzodiazepine prescription use contributes significantly to the overall population's risk of opioid overdose. Currently, however, no measure exists to assess nationwide rates of the concurrent prescribing of opioids and benzodiazepines at the hospital-level.[435] Adopting the Safe Use of Opioids—Concurrent Prescribing eCQM would thus enhance the information available to providers in this area of high-risk prescribing. In addition, we believe the measure is a valuable patient safety measure that has the potential to reduce preventable mortality and other adverse events associated with prescription opioid use, with minimal implementation costs.

The measure is intended to facilitate safer patient care not only by promoting adherence to recommended clinical guidelines on concurrent prescribing practices, but also by incentivizing hospitals to develop strategies to identify and monitor patients on concurrent opioids and opioid-benzodiazepine prescriptions who might be at higher risk of adverse drug events. For instance, the measure could encourage hospital prescribers to use data from prescription drug-monitoring programs when assessing whether to prescribe concurrent substances. The measure could also encourage more effective communication among providers to coordinate care across hospital and ambulatory care settings. The measure could also help establish a national benchmark of opioid prescribing in hospital inpatient settings.

(c) Data Sources

The proposed measure is an eCQM that uses data collected through EHRs to determine hospital performance. Between July 2016 and July 2017, the Safe Use of Opioids—Concurrent Prescribing measure was tested at three health systems (eight hospitals in total) with two different EHR systems for reliability, validity, and feasibility based on the endorsement criteria outlined by NQF.[436] The testing showed that the measure is feasible, valid, and reliable. The measure is feasible as 96 percent of the data elements required to calculate the performance rate are: (1) Collected during routine care; (2) extractable from structured fields in the electronic health systems of test sites; and (3) likely to be accurate. The measure is valid as all data elements needed to calculate the measure had levels of agreement of 84 to 99 percent between electronically extracted and manually abstracted data elements. The measure also has a reliability coefficient of 0.99 across the three health systems' sites with two different EHR systems. This finding indicates that differences in hospital performance reflect true differences in quality, rather than measurement error or noise. For encounters where the patient had at least one active opioid or benzodiazepine prescription at discharge, measure testing also showed concurrent prescribing rates of 18.2 percent in the inpatient setting and 6.1 percent in ED settings. This aligned

[428] List of Measures Under Consideration for December 1, 2016. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[429] 2016–2017 Spreadsheet of Final Recommendations to HHS and CMS. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[430] Measure Applications Partnership, January 2017 NQF MAP Coordinating Committee Meeting Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[431] November 8, 2018 meeting agenda and presentation slides available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[432] National Quality Forum. (2018). *Patient Safety Fall 2017 Final Report.* Available at: *http://www.qualityforum.org/Publications/2018/07/Patient_Safety_Fall_2017_Final_Report.aspx.*

[433] Ibid.

[434] Ibid.

[435] The Veterans Health Administration (VHA), as part of its Opioid Safety Initiative, implemented a measure of concurrent opioid and benzodiazepine prescribing that is similar to the Safe Use of Opioids—Concurrent Prescribing measure. The Opioid Safety Initiative was associated with a decrease in patients receiving benzodiazepine concurrently with an opioid—specifically, a recent study showed a 20.67 percent decrease overall and a 0.86 percent decrease in patients per month (781 patients per month)—among all adult VHA patients who filled outpatient opioid prescriptions from October 2012 to September 2014. *See* Lin, L.A., Bohnert, A.S., Kerns, R.D., Clay, M.A., Ganoczy, D. & Ilgen, M.A. (2017). Impact of the Opioid Safety Initiative on Opioid-Related Prescribing in Veterans. *Pain,* 158(5): 833–39.

[436] National Quality Forum. What NQF Endorsement Means. Available at: *http://www.qualityforum.org/Measuring_Performance/ABCs/What_NQF_Endorsement_Means.aspx.*

with the rates found in the literature. We note that NQF reviewed these data as part of their measure endorsement process and endorsed the measure in 2018.[437]

(d) Measure Calculation

The Safe Use of Opioids—Concurrent Prescribing eCQM is a process measure that calculates the proportion of patients age 18 years and older prescribed two or more opioids or an opioid and benzodiazepine concurrently at discharge from a hospital-based encounter (inpatient or emergency department [ED], including observation stays). An improvement in quality of care is indicated by a decrease in the measure score. We recognize that there may be some clinically appropriate situations for concurrent prescriptions of two unique opioids or an opioid and benzodiazepine. Thus, we do not expect the measure rate to be zero; rather, the goal of the measure is to help systems identify and monitor patients at risk, and ultimately, to reduce the risk of harm to patients across the continuum of care.

The measure's cohort includes all patients aged 18 years and older who were prescribed a new or continued opioid or a benzodiazepine at discharge from a hospital-based encounter (inpatient stay less than or equal to 120 days or ED encounters, including observation stays) that ended during the measurement period. To reduce hospital burden, the definition of ''hospital-based encounter'' is aligned with that of other eCQMs in the Hospital IQR Program.

Patients are included in the numerator if their discharge medications include two or more active opioids or an active opioid and benzodiazepine resulting in concurrent therapy at discharge from the hospital-based encounter.

Patients are included in the denominator if they were discharged from a hospital-based encounter during the measurement period (which includes inpatient stays less than or equal to 120 days or ED visits, including observation stays) and their medications at discharge included a new or continued Schedule II or III opioid, or a new or continued Schedule IV benzodiazepine prescription. Patients are excluded from the denominator if they have an active diagnosis of cancer or order for palliative care (including comfort measures, terminal care, dying care, and hospice care) during the encounter. These exclusions align with the populations excluded from the *2016 CDC Guideline for Prescribing Opioids for Chronic Pain.*

We note risk adjustment is not applicable to the Safe Use of Opioids—Concurrent Prescribing eCQM because it is a process measure. The measure addresses any difference in risk levels for patients via the current denominator exclusions as supported by the available evidence, that is, the measure excludes patients with cancer or patients receiving palliative care.

For more information about the Safe Use of Opioids—Concurrent Prescribing eCQM, we refer readers to the measure specifications.[438]

We also refer readers to section VIII.A.10.d.(1) through (4) of the preamble of this proposed rule where we discuss our proposed eCQM reporting and submission requirements through the CY 2022 reporting period/FY 2024 payment determination, including proposing that all participating hospitals report the Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) as one of the four required eCQMs beginning with the CY 2022 reporting period/FY 2024 payment determination. In addition, we refer readers to section VIII.D.6.a. and b. of the preamble of this proposed rule for a similar proposal to adopt the Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) for the Promoting Interoperability Program beginning with the reporting period in CY 2021.

(2) Hospital Harm—Opioid-Related Adverse Events eCQM

(a) Background

Opioids are among the most frequently implicated medications in adverse drug events among hospitalized patients. The most serious opioid-related adverse events include those with respiratory depression, which can lead to brain damage and death. Opioid-related adverse events have both negative impact on patients and financial implications. Patients who experience adverse events due to opioid administration have been noted to have 55 percent longer lengths of stay, 47 percent higher costs, 36 percent higher risk of 30-day readmission, and 3.4 times higher payments than patients without these adverse events.[439] While noting that data are limited, The Joint Commission suggested that opioid-induced respiratory arrest may contribute substantially to the 350,000 to 750,000 in-hospital cardiac arrests annually.[440]

Most opioid-related adverse events are preventable. Of the opioid-related adverse drug events reported to The Joint Commission's Sentinel Event database, 47 percent were due to a wrong medication dose, 29 percent due to improper monitoring, and 11 percent due to other causes (for example, medication interactions and/or drug reactions).[441] In addition, in a review of cases from a malpractice claims database in which there was opioid-induced respiratory depression among post-operative surgical patients, 97 percent of these adverse events were judged preventable with better monitoring and response.[442] While hospital quality interventions such as proper dosing, adequate monitoring, and attention to potential drug interactions that can lead to overdose are key to prevention of opioid-related adverse events, the use of these practices can vary substantially across hospitals.

Administration of opioids also varies widely by hospital, ranging from 5 percent in the lowest-use hospital to 72 percent in the highest-use hospital.[443] Notably, hospitals that use opioids most frequently have increased adjusted risk of severe opioid-related adverse events.[444] We have developed the Hospital Harm—Opioid-Related Adverse Events eCQM to assess the rates of adverse events as well as the variation in rates among hospitals. In the FY 2019 IPPS/LTCH PPS rulemaking (83 FR 20493 through 20494; 83 FR 41588 through 41592), we solicited public comment on the potential future adoption of this measure.

(b) Overview of Measure

The Hospital Harm—Opioid-Related Adverse Events eCQM is an outcome measure focusing specifically on opioid-related adverse events during an

[437] National Quality Forum. (2018). *Patient Safety, Fall 2017 Final Report.* Available at: *http://www.qualityforum.org/Publications/2018/07/Patient_Safety_Fall_2017_Final_Report.aspx.*

[438] Ibid.

[439] Kessler, E.R., Shah, M., Gruschkkus, S.K., et al. (2013). Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. *Pharmacotherapy,* 33(4): 383–91.

[440] Overdyk, F.J. (2009). Postoperative Respiratory Depression and Opioids. *Initiatives in Safe Patient Care.*

[441] The Joint Commission. (2012.) Safe Use of Opioids in Hospitals. *The Joint Commission Sentinel Event Alert,* 49:1–5.

[442] Lee, L.A., Caplan, R.A., Stephens, L.S., et al. (2015). Postoperative opioid-induced respiratory depression: a closed claims analysis. *Anesthesiology,* 122(3): 659–65.

[443] Herzig, S.J., Rothberg, M.B., Cheung, M., et al. (2014). Opioid utilization and opioid-related adverse events in nonsurgical patients in US hospitals. *Journal of Hospital Medicine,* 9(2): 73–81.

[444] Ibid.

admission to an acute care hospital by assessing the administration of naloxone. Naloxone is a lifesaving emergent therapy with clear and unambiguous applications in the setting of opioid overdose.[445] [446] [447] [448] Naloxone administration has also been used in a number of studies as an indicator of opioid-related adverse events to indicate a harm to a patient during inpatient admission to a hospital.[449] [450] The intent of this measure is for hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and to avoid harm, such as respiratory depression, which can lead to brain damage and death. This measure focuses specifically on in-hospital opioid-related adverse events, rather than opioid overdose events that happen in the community and may bring a patient into the emergency department.

As we state below, this measure would be added to the eCQM measure set from which hospitals could choose to report. For hospitals that select this measure, the measure would provide them with measurement of opioid-related adverse event rates and incentivize improved clinical workflows and monitoring when administering opioids.

The goal of this measure is to incentivize hospitals to closely monitor patients who receive opioids during their hospitalization to prevent respiratory depression. The measure requires evidence of hospital opioid administration prior to the naloxone administration during the first 24 hours after hospital arrival to ensure that the harm was hospital acquired and not due to an overdose that happened outside of the hospital. In addition, the aim of this measure is not to identify preventability of an individual harm instance or whether each instance of harm was an error, but rather to assess the overall rate of harm within a hospital by incorporating a definition of harm that is likely to be reduced as a result of hospital best practice.

The Hospital Harm—Opioid-Related Adverse Events measure (MUC17–210) was included in the publicly available ''List of Measures Under Consideration for December 1, 2017.'' [451] The measure was reviewed by the NQF MAP Hospital Workgroup in December 2017, and received the recommendation to refine and resubmit prior to rulemaking, as referenced in the ''2017–2018 Spreadsheet of Final Recommendations to HHS and CMS.'' [452] The MAP acknowledged the significant health risks associated with opioid-related adverse events but recommended adjusting the numerator to consider the impact on chronic opioid users.[453] Patients on chronic opioids remain at risk of preventable over- or mis-administration of opioids in the hospital and ideally would remain in the measure cohort. This decision was supported by the TEP during measure development. In addition, although chronic opioid users may require higher doses of opioids to achieve adequate pain control, providers have the ability to apply appropriate monitoring to prevent severe adverse events requiring naloxone administration.

In response to the MAP's concerns that the measure needed to be tested in more facilities to demonstrate reliability and validity, we have completed testing the Measure Authoring Tool (MAT) [454] output for this measure in multiple hospitals that use a variety of EHR systems,[455] and the measure was shown to be feasible to implement, reliable, and valid. For more information on the concerns and considerations raised by the MAP related to this measure, we refer readers to the December 2017 NQF MAP Hospital Workgroup Meeting Transcript.[456] In response to the MAP's recommendation, the measure was refined and presented to the MAP on November 8, 2018 for any additional feedback; however, there was no additional MAP feedback at that time.

This measure was submitted for endorsement by NQF's Patient Safety Standing Committee for the Spring 2019 cycle, with a complete review of measure validity and reliability scheduled for June 2019. However, we also note that section 1866(b)(3)(B)(viii)(IX)(bb) of the Act provides an exception under which, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We believe this measure will provide hospitals with reliable and timely measurement of their opioid-related adverse event rates, which are a high-priority measurement area. We believe implementation of this measure can lead to safer patient care by incentivizing hospitals to implement or refine clinical workflows that facilitate evidence-based use and monitoring when administering opioids. We also believe implementation of this measure may result in fewer patients experiencing adverse events associated with the administration of opioids, such as respiratory depression, which can lead to brain damage and death. This measure addresses the quality priority of ''Making Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Preventable Harm.'' [457] We also note

[445] Surgeon General's Advisory on Naloxone and Opioid Overdose. Available at: *https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html.*

[446] Agency for Healthcare Research and Quality (AHRQ). (2017). *Management of Suspected Opioid Overdose with Naloxone by Emergency Medical Services Personnel.* Comparative Effectiveness Review No. 193. Available at: *https://effectivehealthcare.ahrq.gov/topics/emt-naloxon/systematic-review.*

[447] Substance Abuse and Mental Health Services Administration (SAMHSA). (2018). *Opioid Overdose Prevention Toolkit: Information for Prescribers.* Available at: *https://store.samhsa.gov/system/files/information-for-prescribers.pdf.*

[448] Harm Reduction Coalition. (2012). *Guide To Developing and Managing Overdose Prevention and Take-Home Naloxone Projects.* Available at: *https://harmreduction.org/issues/overdose-prevention/tools-best-practices/manuals-best-practice/od-manual/.*

[449] Eckstrand, J.A., Habib, A.S., Williamson, A., et al. (2009). Computerized surveillance of opioid-related adverse drug events in perioperative care: A cross-sectional study. *Patient Safety Surgery,* 3:18.

[450] Nwulu, U., Nirantharakumar, K., Odesanya, R., et al. (2013). Improvement in the detections of adverse drug events by the use of electronic health and prescription records: An evaluation of two trigger tools. *European Journal of Clinical Pharmacology,* 69(2): 255–59.

[451] List of Measures Under Consideration for December 1, 2017. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[452] 2017–2018 Spreadsheet of Final Recommendations to HHS and CMS. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[453] National Quality Forum, Measure Applications Partnership, *MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals.* Available at: *http://www.qualityforum.org/Publications/2018/02/MAP_2018_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx.*

[454] The Measure Authoring Tool (MAT) is a web-based tool used to develop the electronic measure specifications, which expresses complicated measure logic in several formats including a human-readable document. For additional information, we refer readers to: *https://www.emeasuretool.cms.gov/.*

[455] National Quality Forum, Measure Applications Partnership, *MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals.* Available at: *http://www.qualityforum.org/Publications/2018/02/MAP_2018_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx.*

[456] Measure Applications Partnership, December 2017 NQF MAP Hospital Workgroup Meeting Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[457] More information on CMS' Meaningful Measures Initiative is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-*

that adoption of this measure would introduce the first outcomes measure to the eCQM measure set under the Hospital IQR Program, which currently is comprised entirely of process measures.

(c) Data Sources

The data source for this measure is entirely EHR data. The measure is designed to be calculated by the hospitals' EHRs, as well as by CMS using the patient level data submitted by hospitals to CMS. As with all quality measures we develop, testing was performed to confirm the feasibility of the measure, data elements, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Based on testing, results showed that rates of missing data elements required for measure calculation were very low (range 0 percent to 0.8 percent). Testing also showed that the positive predictive value (PPV),[458] which describes the probability that a patient with a positive result (numerator case) identified by the EHR data was also a positive result verified by review of the patient's medical record done by a clinical adjudicator, was high at all hospital testing sites (94 percent to 98 percent). For more information on the measure testing and data, we refer readers to the measure's methodology report on the CMS measure methodology page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* Testing was completed using output from the MAT in five hospitals, using two different EHR systems.

(d) Measure Calculation

The Hospital Harm—Opioid-Related Adverse Events eCQM is an outcome measure that assesses, by hospital, the proportion of patients who had an opioid-related adverse event during an admission to an acute care hospital by assessing the administration of naloxone. The measure includes inpatient admissions that were initiated in the emergency department or in observational status followed by a hospital admission. The measure denominator includes all patients 18 years or older discharged from an inpatient hospital admission during the measurement period.

The numerator is the number of patients who received naloxone outside of the operating room either: (1) After 24 hours from hospital arrival; or (2) during the first 24 hours after hospital arrival with evidence of hospital opioid administration prior to the naloxone administration. We do not include naloxone use in the operating room where it could be part of the sedation plan as administered by an anesthesiologist or nurse anesthetist. Uses of naloxone for procedures outside of the operating room (such as bone marrow biopsy) are counted in the numerator as its use would indicate the patient was over sedated. These criteria exist to ensure patients are not considered to have experienced harm if they receive naloxone in the first 24 hours due to an opioid overdose that occurred in the community prior to hospital arrival. We do not require the administration of an opioid prior to naloxone after 24 hours from hospital arrival because an event occurring 24 hours after admission is most likely due to hospitals' administration of opioids. By limiting the requirement of documented opioid administration to the first 24 hours of the encounter, we are reducing the complexity of the measure logic, and therefore, the burden of implementation for hospitals. The measure numerator identifies a harm using the administration of naloxone, and purposely does not include any medications that combine naloxone with other agents.

The measure is intended to capture a type of rare event, such that a full year of data would most reliably capture the quality of care that is associated with low rates. While reliability of this measure was established using 1 year of data, we note that under the eCQM reporting and submission requirements we are proposing in section VIII.A.10.d.(1) through (4) of the preamble of this proposed rule, initial reporting of this measure, if finalized, would only require hospitals to submit one self-selected calendar quarter of data; hospitals may submit more than one quarter of data for this measure should they so desire. We are considering a 1-year measurement period for the future public reporting of this measure.

(e) Outcome

This eCQM assesses the proportion of encounters where naloxone is administered as a proxy for administration of excessive amounts of opioid medications, not including naloxone given while in the operating room. In the first 24 hours of the hospitalization, an opioid must have been administered prior to receiving naloxone to be considered part of the outcome.

We note this measure is not risk adjusted for chronic opioid use, as most instances of opioid-related adverse events should be preventable for all patients regardless of prior exposure to opioids or chronic opioid use. In addition, there are several risk factors that affect sensitivity to opioids that physicians should consider when dosing opioids. Risk adjustment would only be needed if certain hospitals have patients with distinctly different risk profiles that cannot be mitigated by providing high-quality care. Similarly, the current measure specification does not include stratification of patients for chronic opioid use for three reasons: (1) This is a challenging data element to capture consistently in the EHR; (2) chronic opioid use should be taken into consideration by clinicians in determining dosing in the hospital and theoretically should not be considered a different risk level for patients; and (3) stratification can reduce the effective sample size of a measure and make the measure less useable. During measure development, TEP members gave feedback on whether the measure required risk adjustment. The majority of TEP members voted against risk adjustment of this measure with the rationale that it would be difficult to capture chronic opioid use within the EHR and that the increased risk of harm associated with these patients can be mitigated by hospital monitoring. For more information on the Hospital Harm—Opioid-Related Adverse Events eCQM, we refer readers to the measure specifications available on the CMS Measure Methodology website, at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/measure-methodology.html.*

We also refer readers to section VIII.A.10.d.(1) through (4) of the preamble of this proposed rule where we discuss our proposed eCQM reporting and submission requirements through the CY 2022 reporting period/FY 2024 payment determination. In addition, we refer readers to section VIII.D.6.a. and b. of the preamble of this proposed rule for a similar proposal to adopt the Hospital Harm—Opioid-Related Adverse Events eCQM for the Promoting Interoperability Program beginning with the reporting period in CY 2021.

We acknowledge that some stakeholders have expressed concern that some providers could withhold the use of naloxone for patients who are in respiratory depression, believing that

Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.

[458] ''Predictive Value.'' *Farlex Partner Medical Dictionary.* Available at: *https://medical-dictionary.thefreedictionary.com/predictive+value.*

may help those providers avoid poor performance on the proposed Hospital Harm—Opioid-Related Adverse Events eCQM (83 FR 41591). Therefore, we are soliciting public comment on the potential for this measure to disincentivize the appropriate use of naloxone in the hospital setting or withholding opioids when they are medically necessary in patients requiring palliative care or who are at end of life out of an overabundance of caution.

b. Proposed Adoption of Hybrid Hospital-Wide Readmission Measure With Claims and Electronic Health Record Data (NQF #2879)

In this proposed rule, we are proposing to adopt the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure) into the Hospital IQR Program in a stepwise fashion. First, we would accept data submissions for the Hybrid HWR measure during two voluntary reporting periods. In those periods, we would collect data on the Hybrid HWR measure in accordance with, and to the extent permitted by, the HIPAA Privacy and Security Rules (45 CFR parts 160 and 164, Subparts A, C, and E), and other applicable law. The first voluntary reporting period would run from July 1, 2021 through June 30, 2022, and the second would run from July 1, 2022 through June 30, 2023. These voluntary reporting periods would last for four quarters, which is an expansion upon the 2018 Voluntary Reporting Period for the Hybrid HWR measure, which only collected two quarters of data. Immediately thereafter, we are proposing to require reporting of the Hybrid HWR measure for the reporting period which runs from July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination, and for subsequent years. This proposal to adopt the Hybrid HWR measure with a stepwise implementation timeline is being made in conjunction with our proposal to remove the Claims-Based Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789) (HWR claims-only measure) (discussed in section VIII.A.6. of the preamble of this proposed rule, below). These proposals are discussed in detail below.

(1) Background

Hospital readmission rates are affected by complex and critical aspects of care such as communication between providers or between providers and patients; prevention of, and response to, complications; patient safety; and coordinated transitions to the outpatient environment (82 FR 38350 through 38355). Some readmissions are unavoidable, for example, those that result from inevitable progression of disease or worsening of chronic conditions. However, readmissions may also result from poor quality of care or inadequate transitional care (77 FR 53521). From a patient perspective, an unplanned readmission for any cause is an adverse event. For the July 1, 2016 through June 30, 2017 measurement period (the most recent data available), the readmission rate from the hospital-wide population ranged from 10.6 percent to 20.3 percent, showing a performance gap across hospitals with wide variation and an opportunity to improve quality.[459]

Consistent with our goal of increasing the use of EHR data in quality measurement and in response to stakeholder feedback encouraging the use of clinical data in outcome measures, we developed the Hybrid HWR measure (NQF #2879). The Hybrid HWR measure is designed to capture all unplanned readmissions that arise from acute clinical events requiring urgent rehospitalization within 30 days of discharge. Planned readmissions, which are generally not a signal of quality of care, are not considered readmissions in the measure outcome and all unplanned readmissions are considered an outcome, regardless of cause. The Hybrid HWR measure provides a facility-wide picture of this aspect of care quality in hospitals and was designed to promote hospital quality improvement. The Hybrid HWR measure aligns with the Meaningful Measures Initiative quality priority of ''Promoting Effective Communication and Coordination of Care.''

The Hybrid HWR measure was first included in a publicly available document entitled ''List of Measures Under Consideration for December 1, 2014.'' [460] Upon review, the MAP supported further development of the Hybrid HWR measure, which was an expression of their conditional support pending endorsement for the National Quality Forum (NQF).[461] Thereafter, the Hybrid HWR measure was endorsed by the NQF on December 9, 2016.[462] The Hybrid HWR measure was first discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698 through 49704).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized a 6-month, limited, voluntary reporting period for the EHR-derived data elements used in the Hybrid HWR measure (hereinafter referred to as the 2018 Voluntary Reporting Period). Specifically, for the 2018 Voluntary Reporting Period, we invited participating hospitals and their health IT vendors to report data on discharges over a 6-month period in the first two quarters of CY 2018 (January 1, 2018 through June 30, 2018). We finalized that a hospital's annual payment determination would not be affected by the 2018 Voluntary Reporting Period. Hospitals that participated in the 2018 Voluntary Reporting Period will receive confidential hospital-specific reports in early summer of 2019 that detail submission results from the reporting period, as well as the Hybrid HWR measure results assessed from merged files created by our merging of the EHR data elements submitted by each participating hospital with claims data from the same set of index admissions.

Hospitals that volunteered to submit data increased their familiarity with submitting data for hybrid quality measures from their EHR systems. Participating hospitals received information and instruction on the use of the electronic specifications for this measure, had an opportunity to test extraction and submission of data to CMS, and received submission feedback reports from CMS, available via the QualityNet Secure Portal, with details on the success of their submissions. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38354), we stated that we were considering proposing the Hybrid HWR measure (NQF #2879) as a required measure as early as the FY 2023 payment determination. We also stated that any requirement for mandatory reporting on this measure would be proposed through future rulemaking.

During the 2018 Voluntary Reporting Period, approximately 80 hospitals submitted data for the Hybrid HWR measure. We are currently merging the EHR data with the claims data and will provide hospitals with confidential hospital-specific reports which will

[459] Centers for Medicare & Medicaid Services. (2018). *2018 All-Cause Hospital-Wide Measure Updates and Specifications Report: Hospital-Wide Readmission.* Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[460] List of Measures Under Consideration for December 1, 2014. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[461] Measure Applications Partnership, 2015 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711.*

[462] National Quality Forum. (2017). *All-Cause Admissions and Readmissions 2015–2017 Technical Report.* Available at: *https://www.qualityforum.org/Publications/2017/04/All-Cause_Admissions_and_Readmissions_2015-2017_Technical_Report.aspx.*

reflect submission results from the reporting period. The assessment will be based on the merged files containing both submitted EHR data elements as well as claims data from the same set of index admissions.

We note that the Hybrid HWR measure cohort and outcome are identical to those in the HWR claims-only measure, which was adopted into the Hospital IQR Program beginning with the FY 2015 payment determination (77 FR 53521 through 53528). Therefore, we intend for the Hybrid HWR measure to replace the previously finalized HWR claims-only measure, as further discussed in section VIII.A.6. of the preamble of this proposed rule, where we are proposing to remove the HWR claims-only measure beginning with the July 1, 2023 through June 30, 2024 reporting period, for the FY 2026 payment determination, the same year the Hybrid HWR measure would be required if this proposal is finalized.

(2) Measure Overview

Both the previously finalized HWR claims-only measure and proposed Hybrid HWR measure capture the hospital-level, risk-standardized readmission rate (RSRR) of unplanned, all-cause readmissions within 30 days of hospital discharge for any eligible condition. The measure reports a single summary RSRR, derived from the volume-weighted results of five different models, one for each of the following specialty cohorts based on groups of discharge condition categories or procedure categories: (1) Surgery/gynecology; (2) general medicine; (3) cardiorespiratory; (4) cardiovascular; and (5) neurology. The measure also indicates the hospital-level standardized readmission ratios (SRR) for each of these five specialty cohorts. The outcome is defined as unplanned readmission for any cause within 30 days of the discharge date for the index admission (the admission included in the measure cohort). A specified set of readmissions are planned and do not count in the readmission outcome. The target population is Medicare fee-for-service (FFS) beneficiaries who are 65 years or older and hospitalized in non-federal hospitals.

(3) Data Sources

The Hybrid HWR measure uses a combination of administrative data and a set of core clinical data elements extracted from hospital EHRs for each hospitalized Medicare FFS beneficiary over the age of 65 years, which is why it is referred to as a ''hybrid'' measure. The measure also requires a set of linking variables which are present in both the EHR and claims data, so each patient's core clinical data elements can be matched to the claim for the relevant admission (examples of linking variables are patient unique identifier and patient date of birth).

The administrative data consist of Medicare Part A and Part B claims data and Medicare beneficiary enrollment data, and are used to identify index admissions included in the measure cohort, to create a risk-adjustment model, and to assess the 30-day unplanned readmission outcome. The claims data are merged with EHR-based core clinical data elements, which are routinely collected on hospitalized adults, and are used in this hybrid measure for risk-adjustment of patients' severity of illness. The specific set of core clinical data elements that are used in the Hybrid HWR measure are listed below.

Data elements	Units of measurement	Additional accepted units of measurement
Heart Rate	Beats per minute.	
Systolic Blood Pressure	Millimeter of mercury (mmHg).	
Respiratory Rate	Breath per minute.	
Temperature	Degrees Fahrenheit (F)	Degrees Celsius (C).
Oxygen Saturation	Percent (%).	
Weight	Kilogram (KG)	Pounds (LB).
Hematocrit	Percent (%).	
White Blood Cell Count	10^9 per liter (X10E+09/L)	Thousands of cells per microliter (K/MCL).
Potassium	Millimole per liter (MMOL/L)	MEQ/L.
Sodium	Millimole per liter (MMOL)/L	MEQ/L.
Bicarbonate	Millimole per liter (MMOL)/L	MEQ/L.
Creatinine	Milligrams per deciliter (MG/DL).	
Glucose	Milligrams per deciliter (MG/DL).	

As we stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49703), the core clinical data elements use existing value sets where possible. Because core clinical data elements are data that are routinely collected on hospitalized adults, they are widely available in hospital EHR systems. We have confirmed through testing that extraction of core clinical data elements from hospital EHRs is feasible and can be utilized as part of specific quality outcome measures.[463] The core clinical data elements utilize EHR data, therefore, we developed and tested a MAT output and identified value sets for extraction of the core clinical data elements, which are available at the eCQI Resource Center.[464]

We tested the electronic specifications in four separate health systems that used three different EHR systems. During development and testing of the Hybrid HWR measure, we demonstrated that the core clinical data elements were feasibly extracted from hospital EHRs for nearly all adult patients admitted. We also demonstrated that the use of the core clinical data elements to risk-adjust the Hybrid HWR measure improves the discrimination of the measure, or the ability to distinguish patients with a low risk of readmission from those at high risk of readmission, as assessed by the c-statistic.[465] In addition, inclusion of patients' clinical information from EHRs is responsive to stakeholders who prefer to use clinical information that is available to the clinical care team at the time treatment is rendered to account

[463] For more detail about core clinical data elements used in the Hybrid HWR measure, we refer readers to our discussion in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698 through 49704) and to the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228763452133.*

[464] Electronic Clinical Quality Improvement (eCQI) Resource Center. Hybrid Hospital-Wide Readmission. Available at: *https://ecqi.healthit.gov/ecqm/measures/cms529v0.*

[465] Hybrid 30-day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic Health Record Extracted Risk Factors (Version 1.1); Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1); 164 2013 Core Clinical Data Elements Technical Report (Version 1.1); all available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

for patients' severity of illness rather than relying solely on data from claims (80 FR 49702). The Hybrid HWR measure is now fully developed, tested, and NQF-endorsed (NQF #2879).

We note the Hybrid HWR measure was initially developed using claims coded in ICD–9. However, we have identified and tested ICD–10 specifications for all information used in the measure derived from Medicare claims for both the HWR claims-only measure, which is currently in use under the Hospital IQR Program, and for the proposed Hybrid HWR measure. The ICD–10 specifications are identical for both the Hybrid and claims-only HWR measures. Only the Hybrid HWR measure's use of the core clinical data elements in the risk-adjustment model differs between the two measures. Those data elements are not affected by ICD–10 implementation. We update the measure specifications annually for both measures to incorporate new and revised ICD–10 codes effective October 1 of each year after clinical review.

We also clinically and empirically review updates to the Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS) map that incorporate new codes and shifts in CCS categories of existing codes.[466] These updates may impact assignment to HWR sub-cohorts or modify the planned readmission algorithm. For additional details regarding the measure specifications that accommodate ICD–10-coded claims, we refer readers to the 2018 All-Cause Hospital-Wide Measure Updates and Specifications Report, which is posted on the QualityNet website.[467] We will update and publicly release the MAT output annually to include any updates to the electronic quality measure standards and all included value sets for the measure-specific data elements. We note that the data sources are the same as those used for the 2018 Voluntary Reporting Period.

(4) Measure Calculation

The methods used to calculate the Hybrid HWR measure align with the methods used to calculate the currently adopted HWR claims-only measure. Index admissions are assigned to one of five mutually exclusive specialty cohort groups consisting of related conditions or procedures. An index admission is the hospitalization to which the readmission outcome is attributed and includes admissions for patients:

- Enrolled in Medicare FFS Part A for the 12 months prior to the date of admission and during the index admission;
- Aged 65 or over;
- Discharged alive from a non-federal short-term acute care hospital; and
- Not transferred to another acute care facility.

This measure excludes index admissions for patients:

- Admitted to Prospective Payment System (PPS)-exempt cancer hospitals;
- Without at least 30 days of post-discharge enrollment in Medicare FFS;
- Discharged against medical advice;
- Admitted for primary psychiatric diagnoses;
- Admitted for rehabilitation; or
- Admitted for medical treatment of cancer.

The five specialty cohort groups are: (1) Surgery/gynecology; (2) general medicine; (3) cardiorespiratory; (4) cardiovascular; and (5) neurology. For each specialty cohort group, the standardized readmission ratio (SRR) is calculated as the ratio of the number of ''predicted'' readmissions to the number of ''expected'' readmissions at a given hospital. For each hospital, the numerator of the ratio is the number of readmissions predicted within 30 days based on the hospital's performance with its observed case mix and service mix. The denominator for each hospital is the number of readmissions expected based on the nation's performance with each particular hospital's case mix and service mix. This approach is analogous to a ratio of ''observed'' to ''expected'' used in other types of statistical analyses. The specialty cohort SRRs are then pooled for each hospital using a volume-weighted geometric mean to create a hospital-wide composite SRR. The composite SRR is multiplied by the national observed readmission rate to produce the Risk-Standardized Readmission Rate (RSRR). For additional details regarding the measure specifications to calculate the RSRR, we refer readers to the 2018 All-Cause Hospital-Wide Measure Updates and Specifications Report, which is posted on the QualityNet website.[468]

We also note an important distinguishing factor about hybrid measures: Hybrid measure results must be calculated by CMS to determine hospitals' risk-adjusted rates relative to national rates using data from all reporting hospitals. With a hybrid measure, hospitals submit data extracted from the EHR, and CMS performs the measure calculations and disseminates results.

(5) Outcome

As stated above, the proposed Hybrid HWR measure outcome is aligned with the currently adopted HWR claims-only measure. The Hybrid HWR measure outcome assesses unplanned readmissions for any cause within 30 days of discharge from the index admission. It does not consider planned readmissions as part of the readmission outcome and identifies them by using the CMS Planned Readmission Algorithm, which is a set of criteria for classifying readmissions as planned using Medicare claims. The algorithm for the Hybrid HWR measure[469] is the same algorithm used in the HWR claims-only measure (77 FR 53521).[470] The algorithm and outcomes are also the same as those used for the 2018 Voluntary Reporting Period, although the algorithm is updated annually to reflect changes in the ICD–10 coding system and the CCS map. The algorithm identifies admissions that are typically planned and may occur within 30 days of discharge from the hospital.[471] The most recent version (v 4.0) was described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50211 through 50216) for the HWR claims-only measure, and the code specifications are updated annually. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned procedures and acute diagnoses, can be found in the 2018 All-Cause Hospital-Wide Measure Updates and Specifications Report.[472]

(6) Risk Adjustment

The proposed Hybrid HWR measure adjusts both for case-mix differences

[466] *https://www.hcup-us.ahrq.gov/toolssoftware/ccs10/ccs10.jsp.* Version 2019.1 of CCS for ICD–10–CM and CCS for ICD–10 for PCS.

[467] Centers for Medicare & Medicaid Services. (2018). 2018 *All Cause Hospital Wide Measure Updates and Specifications Report.* Available at: *https://www.qualitynet.org/dcs/ContentServer?cid=1228774371008&pagename=QnetPublic%2FPage%2FQnetTier4&c=Page.*

[468] Centers for Medicare & Medicaid Services. (2018). *2018 All Cause Hospital Wide Measure Updates and Specifications Report.* Available at: *https://www.qualitynet.org/dcs/ContentServer?cid=1228774371008&pagename=QnetPublic%2FPage%2FQnetTier4&c=Page.*

[469] Centers for Medicare & Medicaid Services. Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[470] Centers for Medicare & Medicaid Services. Measure Methodology. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[471] Ibid.

[472] Centers for Medicare & Medicaid Services. (2018). *2018 All Cause Hospital Wide Measure Updates and Specifications Report.* Available at: *https://www.qualitynet.org/dcs/ContentServer?cid=1228774371008&pagename=QnetPublic%2FPage%2FQnetTier4&c=Page.*

(how severely ill patients are when they are admitted) as well as differences in hospitals' service-mix (the types of conditions that cause patients' admissions). The case-mix variables include patients' ages and comorbidities as well as laboratory test results and vital signs. As listed in detail above, the Hybrid HWR measure specifically uses 13 core clinical data elements from EHRs—seven laboratory test results (hematocrit, white blood cell count, sodium, potassium, bicarbonate, creatinine, glucose) and six vital signs (heart rate, respiratory rate, temperature, systolic blood pressure, oxygen saturation, weight). The use of the core clinical data elements to risk-adjust the Hybrid HWR measure improves the discrimination of the measure, and inclusion of patients' clinical information from EHRs is responsive to stakeholders who prefer to use clinical information that is available to the clinical care team at the time treatment is rendered to account for patients' severity of illness rather than relying solely on data from claims (80 FR 49702).

The service-mix variables include principal discharge diagnoses grouped into AHRQ Clinical Classification Software. Patient comorbidities are based on the index admission, the admission included in the measure cohort, and a full year of prior history. The risk-adjustment variables included in the development and testing of the proposed Hybrid HWR measure are derived from both claims and clinical EHR data. As identified in the measure specifications, the variables are: (1) 13 core clinical data elements derived from hospital EHRs;[473] (2) the Clinical Classification Software (CCS) categories[474] for the principal discharge diagnosis associated with each index admission derived from ICD–10 codes in administrative claims data; and (3) comorbid conditions of each patient identified from inpatient claims in the 12 months prior to and including the index admission derived from ICD–10 codes and grouped into the CMS condition categories (CC).[475] The condition categories used in the risk-adjustment model and the ICD–10 codes grouped into each condition category can be found in the Annual Updates and Specification Report on the QualityNet website.

All 13 core clinical data elements were shown to be statistically significant predictors of readmission in one or more risk-adjustment models of the five specialty cohort groups used to calculate the proposed Hybrid HWR measure.[476] The testing results demonstrate that the core clinical data elements enhanced the discrimination (assessed using the c-statistic) when used in combination with administrative claims data.[477] For additional details regarding the risk-adjustment model, we refer readers to the Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1).[478] We note that the risk adjustment methods are the same as those used for the 2018 Voluntary Reporting Period.

(7) Data Submission

As with the 2018 Voluntary Reporting Period (82 FR 38350 through 38355), we are proposing that hospitals would use Quality Reporting Data Architecture (QRDA) Category I files for each Medicare FFS beneficiary who is 65 years and older. Submission of data to CMS using QRDA I files is the current EHR data and measure reporting standard adopted for eCQMs implemented in the Hospital IQR Program. This same standard would be used for reporting the core clinical data elements to the CMS data receiving system via the QualityNet Secure Portal.

To successfully submit the Hybrid HWR measure, hospitals would need to submit the core clinical data elements included in the Hybrid HWR measure, as described in the measure specifications, for all Medicare FFS beneficiaries 65 and older discharged from an acute care hospitalization in the 1-year measurement period (July 1 to June 30 of each year). We note this is the same measurement period as the HWR claims-only measure (77 FR 53521 through 53528). Voluntary submission would run from July 1, 2021 through June 30, 2022, and from July 1, 2022 through June 30, 2023. Required submission would begin with the reporting period which runs July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination.

Hospitals would also be required to successfully submit the following six linking variables that are necessary in order to merge the core clinical data elements with the CMS claims data to calculate the measure:

- CMS Certification Number;
- Health Insurance Claims Number or Medicare Beneficiary Identifier;
- Date of birth;
- Sex;
- Admission date, and
- Discharge date.

In order for us to be able to calculate the Hybrid HWR measure results, each hospital would need to report vital signs for 90 percent or more of the hospital discharges for Medicare FFS patients, 65 years or older in the measurement period (as determined from the claims submitted to CMS for admissions that ended during the same reporting period). Vital signs are measured on nearly every adult patient admitted to an acute care hospital and should be present for nearly 100 percent of discharges (identified in Medicare FFS claims submitted during the same period). In addition, calculating the measure with more than 10 percent of hospital discharges missing these data elements could cause poor reliability of the measure score and instability of hospitals' results from measurement period to measurement period.

Hospitals would also be required to submit the laboratory test results for 90 percent or more of discharges for non-surgical patients,[479] meaning those not included in the surgical specialty cohort of the HWR measure. For many patients admitted following elective surgery, there are no laboratory values available in the appropriate time window. Therefore, laboratory test results are not used in the risk adjustment of the surgical cohort.

The six variables required for linking EHR and claims data should be submitted for 100 percent of discharges in the measurement period. Because these linking variables are required for

[473] Electronic Clinical Quality Improvement (eCQI) Resource Center. Hybrid Hospital-Wide Readmission. Available at: *https://ecqi.healthit.gov/ecqm/measures/cms529v0.*

[474] Centers for Medicare & Medicaid Services. (2018). *2018 All-Cause Hospital-Wide Measure Updates and Specifications Report: Hospital-Wide Readmission.* Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[475] Centers for Medicare & Medicaid Services. (2018). *2018 All-Cause Hospital-Wide Measure Updates and Specifications Report: Hospital-Wide Readmission.* Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[476] Centers for Medicare & Medicaid Services. Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[477] Centers for Medicare & Medicaid Services. Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[478] Ibid.

[479] Centers for Medicare & Medicaid Services. (2018). *2018 All-Cause Hospital-Wide Measure Updates and Specifications Report: Hospital-Wide Readmission.* Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

billing,[480] they should be available on all Medicare FFS patients and are ideally suited to support merging claims and EHR data. However, hospitals would meet Hospital IQR Program requirements if they submit linking variables on 95 percent or more of discharges with a Medicare FFS claim for the same hospitalization during the measurement period. Beginning with the reporting period which runs from July 1, 2023 through June 30, 2024, a hospital that does not submit any EHR data for the Hybrid HWR measure, or that submits data for less than the specified percentage of applicable patients, would be considered as not having met this Hospital IQR Program requirement and would receive a one-fourth reduction of its Annual Payment Update (APU) for the applicable fiscal year.

Under our stepwise approach, for the voluntary reporting periods which run from July 1, 2021 through June 30, 2022, and July 1, 2022 through June 30, 2023, if a hospital submits data for this proposed measure, it should do so according to the requirements described above in order for CMS to calculate the measure. However, a hospital's annual payment determination would not be affected during this timeframe. The benefits to hospitals that submit the data in the initial 2-year voluntary reporting period include the opportunity to provide feedback on the measure specifications, to confirm mapping and extraction of data elements, to hone and improve quality assurance practices, and to troubleshoot any problems populating QRDA templates for successful submission to CMS. As described above, hospitals would receive detailed patient discharge information which would help them perfect these processes before hospitals' payment determinations would be impacted beginning with the FY 2026 payment determination. We refer readers to section VIII.A.10.e. of the preamble of this proposed rule for more information about the form and manner of hybrid measure data submission.

(8) Confidential Feedback Reports

Hospitals that submit data for this measure during the voluntary reporting periods, which run from July 1, 2021 through June 30, 2022, and July 1, 2022 through June 30, 2023, would receive confidential hospital-specific reports that detail submission results from the applicable reporting period, as well as the Hybrid HWR measure results assessed from merged files created by our merging of the EHR data elements submitted by each participating hospital with claims data from the same set of index admissions. Participating hospitals would receive information and instructions on the use of the electronic specifications for this measure, have an opportunity to test extraction and submission of data to CMS, and receive feedback reports from CMS, available via the QualityNet Secure Portal, with details on the success of their submissions.

We are proposing to take an incremental approach to implementing this proposed measure in an effort to be responsive to provider and vendor feedback (82 FR 38355), which requested sufficient time to undertake the data mapping, validation, adjustments to clinician workflow (specifically, changes to documentation practices to ensure accurate and complete mapping of the required data elements), and training needed to effectively implement EHR-based quality reporting to CMS. We believe that two additional years of voluntary reporting of the Hybrid HWR measure, in addition to the 2018 Voluntary Reporting Period, would allow hospitals more time to update and validate their systems, to ensure data mapping is accurate and complete, and to implement workflow changes and clinician training as necessary to better prepare for submitting data when the Hybrid HWR measure becomes required beginning with the reporting period which runs from July 1, 2023 through June 30, 2024 (impacting the FY 2026 payment determination) if our proposal is finalized. We believe those hospitals that can implement the Hybrid HWR measure more quickly can have the opportunity to submit their data to CMS and refine their data collection and submission processes. Starting with voluntary and confidential reporting for the Hybrid HWR measure would enable hospitals and their vendors to gain further experience collecting and reporting the core clinical data elements and linking variables so they would be ready for public reporting of the Hybrid HWR measure data on the *Hospital Compare* website starting with the FY 2026 payment determination.

Under our proposal, the first year of voluntary data collection for confidential reporting would be for the July 1, 2021 through June 30, 2022 reporting period. The 12-month measurement period that runs from July 1 through June 30 would be consistent with the calculation of the HWR claims-only measure. To support hospital reporting, we intend to publish the electronic specifications for this reporting period in the 2021 Annual Update[481] in the spring of 2020, providing hospitals and vendors with the electronic specifications approximately 15 months before the beginning of the reporting period on July 1, 2021. We intend to deliver the first set of confidential hospital-specific feedback reports in the spring of 2023, after we merge the EHR data with the associated claims data for the same reporting period, which is historically pulled from CMS' claims data system at the end of September following the end of the reporting period. During the first year of voluntary data collection, which runs from July 1, 2021 through June 30, 2022, we would not publicly report Hybrid HWR measure data, nor would incomplete or non-submission of the EHR data impact hospitals' APU determinations for the FY 2024 payment determination.

The second year of voluntary data collection for confidential reporting would be for the July 1, 2022 through June 30, 2023 reporting period. Similar to the first year of voluntary reporting, hospitals would use the electronic specifications for this reporting period as published in the 2022 Annual Update planned for the spring of 2021. We plan to deliver confidential hospital-specific feedback reports in the spring of 2024, after we merge the EHR data with the associated claims data. As with the first year of voluntary data collection, there would not be any associated public reporting, nor impact on hospitals' APU determinations for the FY 2025 payment determination. As discussed above, hospitals' payment determinations could be affected beginning with the FY 2026 payment determination.

(9) Public Reporting

Under our stepwise approach, data collected specifically during the voluntary reporting periods, which run from July 1, 2021 through June 30, 2022, and July 1, 2022 through June 30, 2023, would not be publicly reported, as mentioned above. However, we are proposing that after the end of the proposed voluntary reporting periods, we would begin public reporting of the Hybrid HWR measure results, beginning with data collected from the July 1, 2023 through June 30, 2024 reporting period, impacting the FY 2026 payment determination. This would be the first

[480] CMS, *Medicare Claims Processing Manual* (100–04). Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs.html.*

[481] Electronic Clinical Quality Improvement (eCQI) Resource Center. 2018 Measure Specifications. Available at: *https://ecqi.healthit.gov/ecqm/measures/cms529v0.* Note that the measure specifications may be further refined in the 2021 Annual Update.

set of Hybrid HWR measure data to be publicly reported on the *Hospital Compare* website, which we anticipate would be included in the July 2025 refresh of *Hospital Compare.* The EHR data would be merged with the associated claims data, and then Hybrid HWR measure results would be shared with hospitals in the confidential hospital-specific feedback reports planned for the spring of 2025, providing hospitals a 30-day review period prior to public reporting. Thereafter, in subsequent reporting years, we would follow a similar operational timeline for EHR data submissions, availability of hospital-specific reports, and public reporting on the *Hospital Compare* website.

We note that this proposal is being made in conjunction with our proposal to remove the Claims-Based Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789) beginning with the FY 2026 payment determination as discussed below. We also refer readers to section VIII.D.6.c. of preamble of this proposed rule, which includes a request for feedback on whether to consider adopting the Hybrid HWR measure for the Promoting Interoperability Program.

6. Proposed Removal of Claims-Based Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789) (HWR Claims-Only Measure)

In this proposed rule, we are proposing to remove the Claims-Based Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789) in conjunction with our proposal to replace the measure by making the Hybrid HWR measure mandatory beginning with the reporting period which runs from July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination. This is discussed in detail below.

The HWR claims-only measure was adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528) for the FY 2015 payment determination and subsequent years, to allow us to provide a broader assessment of the quality of care at hospitals, especially for hospitals with too few disease specific readmissions to count separately.

In this proposed rule, we are proposing to remove the HWR claims-only measure, beginning with the July 1, 2023 through June 30, 2024 reporting period, for the FY 2026 payment determination. As discussed in section VIII.A.5.b. of the preamble of this proposed rule above, the Hybrid HWR measure is an enhanced version of HWR claims-only measure, in that it provides substantive improvement to the current claims-based measure, which is why we are proposing to replace it. The Hybrid HWR measure includes clinical variables in the risk adjustment, which improves face validity of the measure. Furthermore, we have heard from stakeholders that they strongly favor electronic measures over claims-based versions due to the incorporation of clinical data (80 FR 49694).

We are proposing to remove the HWR claims-only measure under removal Factor 3, ''the availability of a more broadly applicable measure (across settings, populations, or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic).'' We took into particular consideration the aspect of removal Factor 3 which emphasizes when there is a different measure that is more proximal in time to desired patient outcomes. Aspects of the Hybrid HWR measure are more proximal in time to desired patient outcomes for this measure because the measurement of the core clinical data elements for each patient in the measure cohort is taken from the beginning of the applicable inpatient stay, in comparison to the claims data used for risk adjustment, which accounts for 1-year preceding admission. In other words, the patient data used for risk adjustment of the Hybrid HWR measure are data that come from the very start of the inpatient stay that is evaluated for a readmission. In addition, as noted above and discussed in detail in section VIII.A.5.b. of the preamble of this proposed rule, the Hybrid HWR measure includes clinical variables in the risk adjustment, which improves face validity of the measure, and is responsive to provider stakeholder feedback strongly in favor of electronic measures over claims-based versions due to the incorporation of clinical data. For these reasons, we are proposing to remove the HWR claims-only measure and replace it with the Hybrid HWR measure.

We refer readers to sections VIII.A.5.b. and VIII.A.10.e. of the preamble of this proposed rule for more detail on our proposals to adopt the Hybrid HWR measure with a stepwise implementation timeline starting with 2 years of voluntary confidential reporting, followed by mandatory data submission and public reporting of the Hybrid HWR measure results beginning with data collected from the July 1, 2023 through June 30, 2024 reporting period, impacting the FY 2026 payment determination. To ensure continuity of public reporting on Hospital-Wide All-Cause Unplanned Readmission measure data, we are proposing to align the removal of the HWR claims-only measure such that its removal aligns with the end of the 2-year confidential reporting period and beginning of the mandatory data submission and public reporting of the Hybrid HWR measure. In short, the Hybrid HWR measure is intended to replace the HWR claims-only measure. Our proposal to remove the HWR claims-only measure is contingent upon our proposals for the Hybrid HWR measure being finalized.

7. Summary of Previously Finalized and Proposed Hospital IQR Program Measures

a. Summary of Previously Finalized Hospital IQR Program Measures for the FY 2022 Payment Determination

The table below summarizes the previously finalized Hospital IQR Program measure set for the FY 2022 payment determination:

MEASURES FOR THE FY 2022 PAYMENT DETERMINATION

Short name	Measure name	NQF No.
National Healthcare Safety Network Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
COMP–HIP–KNEE*++	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
CMS PSI 04	CMS Death Rate among Surgical Inpatients with Serious Treatable Complications	(+)

MEASURES FOR THE FY 2022 PAYMENT DETERMINATION—Continued

Short name	Measure name	NQF No.
Claims-Based Mortality Measures		
MORT–30–STK	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC–01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED–2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC–05	Exclusive Breast Milk Feeding	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS**	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure).	0166 (0228)

*Finalized for removal from the Hospital IQR Program beginning with the FY 2023 payment determination, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41558 through 41559).

**In the CY 2019 OPPS/ASC PPS final rule with comment period (83 FR 59140 through 59149), we finalized removal of the Communication About Pain questions from the HCAHPS Survey effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years.

+Measure is no longer endorsed by the NQF, but was endorsed at time of adoption. Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the inpatient setting.

++We have updated the short name for the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure (NQF #1550) measure from Hip/Knee Complications to COMP–HIP–KNEE in order to maintain consistency with the updated Measure ID and hospital reports for the *Hospital Compare* website.

b. Summary of Previously Finalized and Newly Proposed Hospital IQR Program Measures for the FY 2023 Payment Determination

The table below summarizes the previously finalized and newly proposed Hospital IQR Program measure set for the FY 2023 payment determination:

MEASURES FOR THE FY 2023 PAYMENT DETERMINATION

Short name	Measure name	NQF No.
National Healthcare Safety Network Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
CMS PSI 04	CMS Death Rate among Surgical Inpatients with Serious Treatable Complications	(+)
Claims-Based Mortality Measures		
MORT–30–STK	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM–30–HWR*	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789

MEASURES FOR THE FY 2023 PAYMENT DETERMINATION—Continued

Short name	Measure name	NQF No.
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC–01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED–2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
Harm—ORAE **	Hospital Harm—Opioid-Related Adverse Events	(++)
PC–05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids **	Safe Use of Opioids—Concurrent Prescribing	3316e
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure).	0166 (0228)

* In section VIII.A.6. of the preamble of this proposed rule, we are proposing to remove the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and in VIII.A.5.b. of the preamble of this proposed rule we are proposing to replace it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination. The proposed removal of the HWR claims-only measure is contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We are proposing to align the removal of the HWR claims only measure such that its removal aligns with the end of the proposed 2-year voluntary reporting period and the beginning of the proposed mandatory data submission and public reporting of the Hybrid HWR measure.

** Newly proposed in this proposed rule to add to the eCQM measure set, beginning with the CY 2021 reporting period/FY 2023 payment determination.

+ Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the inpatient setting.

++ This measure was submitted for endorsement by NQF's Patient Safety Standing Committee for the Spring 2019 cycle, with a complete review of measure validity and reliability current scheduled for June 2019.

8. Potential Future Quality Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512), we outlined considerations to guide us in selecting new quality measures to adopt into the Hospital IQR Program. We also refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), where we describe the Meaningful Measures Initiative and the quality priorities and high impact measurement areas under the Meaningful Measures framework that we have identified as relevant and meaningful to both patients and providers. In keeping with these considerations, we are inviting public comment on the possible future inclusion of the following three measures in the Hospital IQR Program. We note that these measures are also being considered for potential future inclusion in the Promoting Interoperability Program.

a. Hospital Harm—Severe Hypoglycemia eCQM

(1) Background

Hypoglycemic events in the hospital are among the most common adverse drug events.[482] Hypoglycemia can cause a wide range of symptoms, including mild symptoms of dizziness, sweating, and confusion to more severe symptoms such as seizure, tachycardia or loss of consciousness. Most individuals with hypoglycemia recover fully, but in rare instances, hypoglycemia can progress to coma and death.[483] Hypoglycemia (defined as a blood glucose level of less than 70 mg/dl in this study) is associated with higher in-hospital mortality, increased length of stay, and consequently, increased resource use.[484] In a 2003–2004 study examining clinical outcomes associated with hypoglycemia in hospitalized people with diabetes, patients who had at least one hypoglycemic episode (a blood glucose level of less than 50 mg/dL) were hospitalized 2.8 days longer than patients who did not experience hypoglycemia.[485] Another retrospective cohort study showed hospitalized patients with diabetes who experienced

[482] Office of Disease Prevention and Health Promotion. (2014). National Action Plan for Adverse Drug Event Prevention. Available at: *https://health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf.*

[483] Diabetes Control and Complications Trial Research Group. (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine,* 329(14): 977–86.

[484] Krinsley, J.S., Schultz, M.J., Spronk, P.E., van Braam Houckgeest, F., van der Sluijs, J.P., Melot, C. & Preiser, J.C. (2011). Mild hypoglycemia is strongly associated with increased intensive care unit length of stay. *Ann Intensive Care,* 1, 49.

[485] Turchin, A., Matheny, M.E., Shubina, M., Scanlon, J.V., Greenwood, B., & Pendergrass, M.L. (2009). Hypoglycemia and clinical outcomes in patients with diabetes hospitalized in the general ward. *Diabetes Care,* 32(7): 1153–57.

hypoglycemia (a blood glucose level of less than 70 mg/dL) had higher medical costs (by 38.9 percent), longer length of stay (by 3.0 days), and higher odds of being discharged to a skilled nursing facility (odds ratio 1.58; 95 percent Confidence Interval 1.48–1.69) than patients with diabetes without hypoglycemia (p<0.01 for all).[486]

The rate of severe hypoglycemia (a blood glucose level of less than 40 mg/dL) varies across hospitals indicating an opportunity for improvement in care. Severe hypoglycemia rates have been reported to range from 2.3 percent to 5 percent of hospitalized patients with diabetes, and from 0.4 percent of non-ICU patient days to 1.9 percent of ICU patient days.[487] [488] [489] Severe hypoglycemic events are largely avoidable by careful use of anti-diabetic medication and close monitoring of blood glucose values.

Although there are many occurrences of hypoglycemia in hospital settings, many of which are preventable, there is currently no measure in a CMS quality program that quantifies how often hypoglycemic events happen to patients while in inpatient acute care. AHRQ identified insulin and other hypoglycemic agents as high-alert medications and associated adverse drug events to be included as a measure in the Medicare Patient Safety Monitoring System (MPSMS),[490] signifying the importance of measuring this hospital harm. Unlike the MPSMS which relies on chart abstracted data, the Hospital Harm—Severe Hypoglycemia eCQM identifies hypoglycemic events using direct extraction of structured data from the EHR. In addition, the National Action Plan for Adverse Drug Event Prevention notes the opportunity for health care quality reporting measures and meaningful utilization of EHR data to advance hypoglycemic adverse drug event prevention.[491] To address these gaps in measurement, we developed the Hospital Harm—Severe Hypoglycemia eCQM to identify the rates of severe hypoglycemic events using direct extraction of structured data from the EHR. We believe this measure will provide reliable and timely measurement of the rate at which severe hypoglycemia events occur in the setting of hospital administration of medication during hospitalization, which will create transparency for providers and patients with respect to variation in rates of these events among hospitals.

(2) Overview of Measure

The Hospital Harm—Severe Hypoglycemia eCQM is an outcome measure focusing specifically on in-hospital severe hypoglycemic events in the setting of hospital administered antihyperglycemic medications. The measure identifies the proportion of patients who experienced a severe hypoglycemic event using a low glucose test result of less than 40 mg/dL, within 24 hours of the administration of an antihyperglycemic agent, which indicates harm to a patient. The intent of this measure is for hospitals to track and improve their practices of appropriate dosing and adequate monitoring of patients receiving glycemic control agents, and to avoid patient harm leading to increased risk of mortality and disability. This measure addresses the quality priority of ''Making Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measure Area of ''Preventable Healthcare Harm.'' [492]

This measure is a respecification of a measure of hypoglycemia originally endorsed by the NQF, Glycemic Control—Severe Hypoglycemia (NQF #2363).[493] The original measure was not implementable because the MAT could not support the measure as specified when it was originally developed due to limitations in the Quality Data Model (QDM) to express the measure logic or syntax as specified. The measure was respecified using the updates to the MAT including expression of the logic with CQL to create a measure that can now be implemented.

The Hospital Harm—Severe Hypoglycemia (MUC18–109) measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2018.'' [494] This measure was reviewed by the NQF MAP Hospital Workgroup in December 2018 and received conditional support pending NQF review and reendorsement once the revised measure is fully tested.[495] [496] MAP stakeholders agreed that severe hypoglycemia events are largely avoidable by careful use of antihyperglycemic medication and blood glucose monitoring. The MAP recommended continuously assessing the low blood glucose threshold of <40mg/dL for defining harm events to assess unintended consequences. Other recommendations from the MAP included defining the numerator as the total number of hypoglycemia events per hospitalization instead of the current numerator definition as a count of hospitalizations with at least one hypoglycemia event. The numerator definition was discussed at length with the measure TEP during development. The TEP members agreed with the current numerator definition of a count of hospitalizations with at least one hypoglycemic event because this adequately captures differences in quality among hospitals while simultaneously minimizing measure burden by not requiring hospitals to extract every single hypoglycemic event during a hospitalization. We agree with the importance of continually monitoring for unintended consequences once this measure is implemented. We recognize the importance of measuring hyperglycemia in conjunction with hypoglycemia and are currently developing a severe hyperglycemia eCQM. For additional information and discussion of concerns and considerations raised by the MAP related to this measure, we refer readers to the December 2018 NQF MAP

[486] Curkendall, S.M., Natoli, J.L., Alexander, C.M., Nathanson, B.H., Haidar, T., & Dubois, R.W. (2009). Economic and clinical impact of inpatient diabetic hypoglycemia. *Endocrine Practice,* 15(4): 302–312.

[487] Nirantharakumar, K., Marshall, T., Kennedy, A., Narendran, P., Hemming, K., & Coleman, J.J. (2012). Hypoglycemia is associated with increased length of stay and mortality in people with diabetes who are hospitalized. *Diabetic Medicine,* 29(12): e445–e448.

[488] Wexler, D.J., Meigs, J.B., Cagliero, E., Nathan, D.M., & Grant, R.W. (2007). Prevalence of hyper- and hypoglycemia among inpatients with diabetes: A national survey of 44 U.S. hospitals. *Diabetes Care,* 30(2): 367–369.

[489] Cook, C.B., Kongable, G.L., Potter, D.J., Abad, V.J., Leija, D.E., & Anderson, M. (2009). Inpatient glucose control: A glycemic survey of 126 U.S. hospitals. *Journal of Hospital Medicine,* 4(9): E7–E14.

[490] Classen, DC, Jaser, L., Budnitz, D.S. (2010). Adverse Drug Events among Hospitalized Medicare Patients: Epidemiology and national estimates from a new approach to surveillance. *Joint Commission Journal on Quality and Patient Safety,* 36(1): 12–21.

[491] Office of Disease Prevention and Health Promotion. (2014). National Action Plan for Adverse Drug Event Prevention. Available at: *https://health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf.*

[492] More information on CMS' Meaningful Measures Initiative can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[493] For more information on the Glycemic Control—Severe Hypoglycemia measure, we refer readers to the measure specifications, available at: *http://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=2363&print=1&entityTypeID=1.*

[494] List of Measures Under Consideration for December 1, 2018. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[495] 2018–2019 Spreadsheet of Final Recommendations to HHS and CMS. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[496] National Quality Forum, Measure Applications Partnership, *MAP 2019 Considerations for Implementing Measures in Federal Programs: Hospitals.* Available at: *http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx.*

Hospital Workgroup meeting transcript.[497] This measure was submitted for endorsement by NQF's Patient Safety Standing Committee for the Spring 2019 cycle, with a complete review of measure validity and reliability currently scheduled for June 2019.

(3) Data Sources

The data source for this measure is entirely EHR data. The measure is designed to be calculated by the hospitals' EHRs as well as by CMS using the patient level data submitted by hospitals to CMS.

As with all quality measures we develop, testing was performed to establish the feasibility of the measure, data elements, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Testing was completed using output from the MAT in multiple hospitals, using multiple EHR systems, with the measure shown to be both reliable and valid.

(4) Measure Calculation

This measure assesses the rate at which severe hypoglycemia events caused by hospital administration of medications occur in the acute care hospital setting. It assesses the proportion of patients who had an antihyperglycemic medication given within the 24 hours prior to the harm event; and a laboratory test for glucose with a result of low glucose (less than 40 mg/dL); and no subsequent laboratory test for glucose with a result greater than 80 mg/dL within 5 minutes of the low glucose result. This measure only counts one severe hypoglycemia event per patient admission.

The measure denominator includes all patients 18 years or older discharged from an inpatient hospital encounter during the measurement period, who were administered at least one antihyperglycemic medication during their hospital stay. The measure includes inpatient admissions for patients initially seen in the emergency department or in observation status and subsequently became an inpatient. There are no denominator exclusions for this measure.

The numerator for this measure is the number of hospitalized patients with a blood glucose test result of less than 40 mg/dL (indicating severe hypoglycemia) with no repeat glucose test result greater than 80 mg/dL within 5 minutes of the low glucose test, and where an antihyperglycemic medication was administered within 24 hours prior to the low glucose result. We counted instances of low glucose of less than 40 mg/dL to identify only severe cases of hypoglycemia. Not including severe hypoglycemic events with a repeat test over 80 mg/dL within 5 minutes is to avoid counting false positives (mostly from point-of-care tests that might have returned an initial erroneous result). There are no numerator exclusions for this measure.

For more information on the Hospital Harm—Severe Hypoglycemia eCQM, we refer readers to the measure specifications available on the CMS Measure Methodology website, at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/measure-methodology.html.*

(5) Outcome

The outcome of interest is to reduce the rate of severe hypoglycemia events caused by hospital administration of medications that occur in the acute care hospital setting.

In evaluating our measures, we generally consider the following criteria in determining whether risk adjustment is warranted: (1) If many patients are at risk of the harm regardless of their age, clinical status, comorbidities, or reason for admission; (2) if the majority of incidents of the harm are linkable to care provision under the control of providers (for example, harms caused by excessive or inappropriate medication dosing); and (3) if there is evidence that the risk of a harm can be largely ameliorated by best care practices regardless of a patient's inherent risk profile. For example, there may be evidence that even complex patients with multiple risk factors can avoid harm events when providers closely adhere to care guidelines.

In the case of the Hospital Harm—Severe Hypoglycemia eCQM, there is evidence indicating that most hypoglycemic events of this severity (<40 mg/dL) are avoidable.[498] [499] [500] [501] Although specific patients may be particularly vulnerable to hypoglycemia in certain settings (for example, due to organ failure and not related to administration of diabetic agents), the most common causes are lack of caloric intake, overuse of anti-diabetic agents, or both. As these causes are controllable in hospital environments, and risk can easily be reduced by following best practices, we do not think risk adjustment is warranted for this measure. We will continue to evaluate the appropriateness of risk adjustment in measure reevaluation.

We are inviting public comment on potential future inclusion of the Hospital Harm—Severe Hypoglycemia eCQM in the Hospital IQR Program, including any potential unintended consequences that might result from future adoption of this measure, as well as ways to address those potential unintended consequences. We note that we are also considering this measure for potential future inclusion in the Promoting Interoperability Program.

b. Hospital Harm—Pressure Injury eCQM

(1) Background

Pressure injuries are a common patient hospital harm and can be serious health events. An estimated 1.19 million hospital acquired pressure injuries occurred in the year 2015.[502] Pressure injuries commonly can lead to local infection, osteomyelitis, anemia, and sepsis,[503] in addition to causing significant depression, pain, and discomfort to patients.[504] The presence or development of a pressure injury can increase the length of a patient's hospital stay by an average of four days, which can increase the spending ranging from $20,900 to $151,700 per pressure injury.[505] [506]

[497] Measure Applications Partnership, December 2018 NQF MAP Hospital Workgroup Meeting Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[498] Cook, C.B., Kongable, G.L., Potter, D.J., Abad, V.J., Leija, D.E., & Anderson, M. (2009). *Inpatient glucose control: A glycemic survey of 126 U.S. hospitals.* Journal of Hospital Medicine, 4(9), E7–E14.

[499] Moghissi, E.S., Korytkowski, M.T., DiNardo, M., et al. (2009). American Association of Clinical Endocrinologists and American Diabetes Association Consensus Statement on Inpatient Glycemic Control. *Diabetes Care,* 32(6):1119–1131.

[500] Office of the Inspector General (OIG). (2010). *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries.*

[501] Wexler, D.J., Meigs, J.B., Cagliero, E., Nathan, D.M., & Grant, R.W. (2007). Prevalence of hyper- and hypoglycemia among inpatients with diabetes: A national survey of 44 U.S. hospitals. *Diabetes Care,* 30(2): 367–69.

[502] Agency for Healthcare Research and Quality. National Scorecard on Rates of Hospital-Acquired Conditions 2010 to 2015: Interim Data From National Efforts to Make Health Care Safer. (2016). Available at: *https://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html?utm_source=AHRQ&utm_medium=PSLS&utm_term=&utm_content=14&utm_campaign=AHRQ_NSOHAC_2016.*

[503] Brem, H., Maggi, J., Nierman, D., Rolnitzky, L., Bell, D., Rennert, R., Golinko, M., Yan, A., Lyder, C., Vladeck, B. (2010). High cost of stage IV. The American Journal of Surgery, 200: 473–477.

[504] Gunningberg, L., Donaldson, N., Aydin, C. & Idvall, E. (2012). Exploring variation in pressure ulcer prevalence in Sweden and the USA: benchmarking in action. *Journal of Evaluation in Clinical Practice,* 18: 904–910.

[505] Agency for Healthcare Research and Quality. National Scorecard on Rates of Hospital-Acquired Conditions 2010 to 2015: Interim Data From

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The rate of pressure injuries varies across hospitals suggesting that there may be opportunity for further improvement. One study of 51,842 patients found that 4.5 percent of patients developed at least one new pressure injury during their hospitalization, with a 3.2 percent between-state variance.[507] Another study revealed pressure injury prevalence rates in U.S. hospitals participating in a registry was 2.0 percent for hospital-acquired pressure injuries,[508] while a third national study found 1.8 percent of inpatients had at least one pressure injury based on ICD–9 codes.[509] Pressure injury is considered a serious reportable event by the NQF,[510] CMS established non-payment for pressure injury,[511] and it is an indicator of the quality of nursing care a hospital provides.[512] It is well-accepted that pressure injury can be reduced through best practices [513] such as frequent repositioning, proper skin care, and specialized cushions or beds.[514] AHRQ published data that showed 3.1 million fewer incidents of hospital-acquired harm in 2011–2015 compared with 2010; 23 percent of this reduction was from a reduction in hospital-acquired pressure injuries.[515] Research has also suggested a link between a hospital's processes of care and the outcome of hospital-acquired pressure injury.[516] We therefore believe that pressure injuries are an important issue to address in the Hospital IQR Program.

(2) Overview of Measure

The intent of the Hospital Harm—Pressure Injury eCQM is to reduce pressure injury prevalence by creating transparency in the rate of these harms which should encourage hospitals to promote best practices such as frequent monitoring of patients at high risk, documenting skin assessments, frequent repositioning, proper skin care, and use of specialized cushions or beds. This measure identifies pressure injuries using direct extraction of structured data from the EHR and will provide hospitals with reliable and timely measurement of their pressure injury rates as well as creating transparency for providers and patients about the variation in rates of these events among hospitals. Pressure injuries staged 3 and staged 4 (or unstageable) are currently measured and publicly reported in the HAC Reduction Program as a component of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure, but this potential Hospital Harm—Pressure Injury measure improves measurement of pressure injuries by using EHR data rather than administrative claims.

The Hospital Harm—Pressure Injury eCQM was included in the publicly available document entitled ''List of Measures Under Consideration for December 1, 2018.'' [517] This measure was reviewed by the NQF MAP Hospital Workgroup in December 2018 and received conditional support pending NQF review and endorsement once the measure is fully tested.[518] The MAP expressed their broad support for the measure and agreed this measure can reduce patient harm due to pressure injury. Recommendations from the MAP included, excluding patients undergoing certain types of treatment that may not be appropriate to receive evidence-based pressure injury reducing interventions, such as patients at the end of life, as well as considering clinical data such as albumin if the measure were to be risk adjusted in the future. The MAP also recommended that the developer consider how multiple pressure injuries are identified and assessed in the same encounter. Based on the evidence gathered during testing and expert input, the measure is currently not risk adjusted and it does not exclude patients with certain conditions from the denominator as evidence shows that most newly acquired pressure injuries can be mitigated through best care and the most common causes of pressure injuries (limited mobility during acute illness, friction against skin) put all hospitalized patients at similar risk.[519] [520] This measure only includes one event per hospitalization, which was supported by the TEP during measure development, to provide a quality signal without imposing undue burden on hospitals to have to enumerate every instance of a pressure injury. However, this measure was submitted for endorsement by NQF's Patient Safety Standing Committee for the Spring 2019 cycle, and these aspects of the measure specifications will be considered during NQF scientific review currently scheduled for June 2019. For additional information and discussion of concerns and considerations raised by the MAP related to the measure, we refer readers to the December 2018 NQF MAP Hospital Workgroup meeting transcript.[521]

National Efforts to Make Health Care Safer. (2016). Available at: *https://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html?utm_source=AHRQ&utm_medium=PSLS&utm_term=&utm_content=14&utm_campaign=AHRQ_NSOHAC_2016.*

[506] Bauer, K., Rock, K., Nazzai, M.J., & Qu, W. (2016). Pressure Ulcers in the United States Inpatient Population from 2008 to 2012: Results of a Retrospective Nationwide Study. *Ostomy Wound Management,* 62(11): 30–38.

[507] Lyder, C.H., Wang, Y., Metersky, M., Curry, M., Kliman, R., Verzier, N.R., Hunt, D.R. (2012). Hospital-acquired pressure ulcers: results from the national Medicare Patient Safety Monitoring System study. *Journal of American Geriatrics Society,* 60(9): 1603–8.

[508] Gunningberg, L., Donaldson, N., Aydin, C. & Idvall, E. (2012). Exploring variation in pressure ulcer prevalence in Sweden and the USA: benchmarking in action. *Journal of Evaluation in Clinical Practice,* 18: 904–910.

[509] Bauer, K., Rock, K., Nazzai, M.J., & Qu, W. (2016). Pressure Ulcers in the United States Inpatient Population from 2008 to 2012: Results of a Retrospective Nationwide Study. *Ostomy Wound Management,* 62(11): 30–38.

[510] National Quality Forum, List of SREs. Available at: *http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx.*

[511] Centers for Medicare & Medicaid Services. Hospital-Acquired Conditions. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html.*

[512] National Quality Forum. (2004). National Voluntary Consensus Standards for Nursing-Sensitive Care: An Initial Performance Measure Set 2005. Available at: *http://www.qualityforum.org/Publications/2004/10/National_Voluntary_Consensus_Standards_for_Nursing-Sensitive_Care__An_Initial_Performance_Measure_Set.aspx.*

[513] Agency for Healthcare Research and Quality. (2012). Preventing Pressure Ulcers in Hospitals: A Toolkit for Improving Quality of Care. Available at: *https://www.ahrq.gov/sites/default/files/publications/files/putoolkit.pdf.*

[514] Gunningberg, L., Donaldson, N., Aydin, C. & Idvall, E. (2012). Exploring variation in pressure ulcer prevalence in Sweden and the USA: benchmarking in action. *Journal of Evaluation in Clinical Practice,* 18: 904–910.

[515] Agency for Healthcare Research and Quality. (2016). National Scorecard on Rates of Hospital-Acquired Conditions 2010–2015: Interim Data From Nation Efforts to Make Health Care Safer. Available at: *https://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html.*

[516] Gunningberg, L., Donaldson, N., Aydin, C. & Idvall, E. (2012). Exploring variation in pressure ulcer prevalence in Sweden and the USA: benchmarking in action. *Journal of Evaluation in Clinical Practice,* 18: 904–910.

[517] List of Measures Under Consideration for December 1, 2018. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[518] 2018–2019 Spreadsheet of Final Recommendations to HHS and CMS. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[519] Gunningberg, L., Donaldson, N., Aydin, C., Idvall, E. (2011). Exploring variation in pressure ulcer prevalence in Sweden and the USA: Benchmarking in action. 18. 10.1111/j.1365–2753.2011.01702.x. Journal of evaluation in clinical practice., 904–910.

[520] Berlowitz, D., VanDeusen Lukas, C., Parker, V., Niederhauser, A., Silver, J., Logan, C., Ayello, E., Zulkowski, K. (2012). Preventing Pressure Ulcers in Hospitals—A Toolkit for Improving Quality of Care.

[521] Measure Application Partnership, 2018 NQF MAP Hospital Workgroup Meeting Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

(3) Data Sources

The data source for this measure is entirely EHR data. The measure is designed to be calculated by the hospitals' EHRs, as well as by CMS using the patient level data submitted by hospitals to CMS.

As with all quality measures we develop, testing was performed to confirm the feasibility of the measure, data elements, and validity of the numerator, using clinical adjudicators who validated the EHR data by comparison to medical chart abstracted data. Testing was completed using output from the MAT in multiple hospitals, using multiple EHR systems, and the measure was shown to be both reliable and valid. In addition, testing showed data element feasibility is higher at hospitals with a designated ''pressure injury'' field in the EHR, as opposed to a generic ''wound'' field.

(4) Measure Calculation

This measure assesses the rate at which new hospital-acquired pressure injuries occur during an acute care hospitalization. It assesses the proportion of encounters with a newly developed stage 2, stage 3, stage 4, deep tissue pressure injury, or unstageable pressure injury during hospitalization.

The measure denominator includes all patients 18 years or older discharged from an inpatient hospital encounter during the measurement period. The measure includes inpatient admissions for patients initially seen in the emergency department or in observation status. There are no exclusions for this measure.

The numerator for this electronic outcome measure is defined as the number of admissions where a patient has a newly-developed pressure injury stage 2, stage 3, stage 4, deep tissue pressure injury, or unstageable pressure injury that was not documented as present in the first 24 hours of hospital arrival. Measure developers and guideline organizations recommend skin assessment within 24 hours of hospital arrival.[522] [523] [524] [525] This measure assumes that any pressure injury not documented within 24 hours of arrival is hospital-acquired. For more information on the Hospital Harm—Pressure Injury eCQM, we refer readers to the measure specifications available on the CMS Measure Methodology website, at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/measure-methodology.html.*

(5) Outcome

The outcome of interest is to reduce the rate at which new hospital-acquired pressure injuries occur during an acute care hospitalization.

In evaluating our measures, we generally consider the following criteria in determining whether risk adjustment is warranted: (1) If many patients are at risk of the harm regardless of their age, clinical status, comorbidities, or reason for admission; (2) if the majority of incidents of the harm are linkable to care provision under the control of providers (for example, harms caused by inappropriate skin care or lack of frequent repositioning); and (3) if there is evidence that the risk of a harm can be largely ameliorated by best care practices regardless of a patient's inherent risk profile. For example, there may be evidence that even complex patients with multiple risk factors can avoid harm events when providers closely adhere to care guidelines.

In the case of the Hospital Harm-Pressure Injury eCQM, there is evidence indicating that most newly acquired pressure injuries are avoidable with best practice.[526] [527] Although specific patients may be particularly vulnerable to pressure injuries in certain settings (for example, permanent or prolonged immobility), the most common causes are limited mobility during an acute illness and friction or shear against sensitive skin. Many hospitalized patients are at risk of these injuries. There are many actions hospitals can take to reduce patient harm risk, such as conducting a structured risk assessment to identify individuals at risk for pressure injury as soon as possible upon arrival and repeating at regular intervals, as well as proper skin care, nutrition, and careful repositioning of patients. As many of the causes can be mitigated through best care in hospital environments, we do not think risk adjustment is warranted for this measure. We will continue to evaluate the appropriateness of risk adjustment in measure reevaluation.

We are inviting public comment on potential future inclusion of the Hospital Harm—Pressure Injury eCQM in the Hospital IQR Program. We are specifically seeking public comment on any unintended consequences that might result from future adoption of this measure, as well as ways to address those potential unintended consequences. We note that we are also considering this measure for potential future inclusion in the Promoting Interoperability Program.

c. Cesarean Birth (PC–02) eCQM (NQF #0471e)

(1) Background

A Cesarean section (C-section) is the use of surgery to deliver a baby (or babies) in lieu of vaginal delivery. The procedure therefore entails surgical and anesthesia risks and requires mothers to undergo several days of inpatient, postoperative recovery. A C-section may occur on an emergency basis or elective basis.[528] Elective C-sections may be necessary due to preexisting medical conditions, such as high blood pressure (preeclampsia), other medical indications, or may be preferred for non-medical reasons. Non-medical reasons for elective C-section can relate to maternal preference, local practice patterns, fear of malpractice litigation, reimbursement anomalies, or other factors.[529] [530] [531]

The total rate of (emergency and elective) C-sections has risen since the 1990s in the United States.[532] C-sections

[522] National Pressure Ulcer Advisory Panel. (2016). NPAUAP Pressure Injury Stages. Available at: *http://www.npuap.org/resources/educational-and-clinical-resources/npuap-pressure-injury-stages/.*

[523] Agency for Healthcare Research and Quality. (2012). Preventing Pressure Ulcers in Hospitals: A Toolkit for Improving Quality of Care. Available at: *https://www.ahrq.gov/sites/default/files/publications/files/putoolkit.pdf.*

[524] Catania, K. et al. (2007). *PUPPI: The Pressure Ulcer Prevention Protocol Interventions.* American Journal of Nursing, 107(4): 44–52.

[525] National Quality Forum. (2004). National Voluntary Consensus Standards for Nursing-Sensitive Care: An Initial Performance Measure Set 2005. Available at: *http://www.qualityforum.org/Publications/2004/10/National_Voluntary_Consensus_Standards_for_Nursing-Sensitive_Care__An_Initial_Performance_Measure_Set.aspx.*

[526] Gunningberg, L., Donaldson, N., Aydin, C., Idvall, E. (2011). Exploring variation in pressure ulcer prevalence in Sweden and the USA: Benchmarking in action. 18. 10.1111/j.1365–2753.2011.01702.x. *Journal of evaluation in clinical practice.,* 904–910.

[527] Berlowitz, D., VanDeusen Lukas, C., Parker, V., Niederhauser, A., Silver, J., Logan, C., Ayello, E., Zulkowski, K. (2012). Preventing Pressure Ulcers in Hospitals—A Toolkit for Improving Quality of Care.

[528] National Quality Forum, Quality Measure PC–02 (Cesarean Birth). Available at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=291&print=1&entityTypeID=1.*

[529] Caughey AB, Cahill AG, Guise JM, Rouse DJ. Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol. 2014 Mar;210(3):179–93. doi: 10.1016/j.ajog.2014.01.026.

[530] Schifrin BS, Cohen WR. The effect of malpractice claims on the use of caesarean section. Best Pract Res Clin Obstet Gynaecol. 2013 Apr;27(2):269–83. doi: 10.1016/j.bpobgyn.2012.10.004. Epub 2012 Dec 1. Review.

[531] Chen CS, Liu TC, Chen B, Lin CL. The failure of financial incentive? The seemingly inexorable rise of cesarean section. Soc Sci Med. 2014 Jan;101:47–51. doi: 10.1016/j.socscimed.2013.11.010. Epub 2013 Nov 15.

[532] Osterman, M.J.K., Martin, J.A. (2014). Trends in Low-risk Cesarean Delivery in the United States,

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accounted for about one-third of U.S. deliveries in 2016,[533] and there is a considerable amount of variation in the rates based on U.S. region, State, and healthcare institution.[534] U.S. practice guidelines have not indicated an optimal rate of C-section or an appropriate variance rate, but international studies suggest a preference for a lower range than current U.S. rates.[535] [536] [537] When medically justified, a C-section can effectively prevent maternal and perinatal mortality and morbidities. However, clinicians and consensus groups agree that increased C-section rates have not improved overall maternal-fetal outcomes and that C-sections are overused.[538] [539] Below, we include literature outlining maternal and neonatal C-section outcomes.

For maternal outcomes, C-sections have significantly higher prenatal and postpartum morbidity and mortality (9.2 percent) than vaginal births (8.6 percent).[540] Existing literature largely does not distinguish whether inferior outcomes derive from cause (higher risk patients undergo C-section) or effect (surgery carries inherent risks due to anesthesia, bleeding, infection, postoperative recovery, etc.). However, taking an aggregate view of multiple studies over time, it appears that C-sections carry a higher risk of subsequent miscarriage, placental abnormalities, and repeat C-section.[541] Conversely, urinary incontinence and pelvic organ prolapse occur less frequently after C-section than after vaginal delivery.[542]

In terms of neonatal outcomes, C-sections have higher respiratory morbidity (1 to 4 percent) than vaginal births (<1 percent).[543] Children delivered by C-section also have a higher risk of asthma and obesity.[544] However, C-sections have better outcomes for shoulder dystocia (0 percent versus 1–2 percent).[545] Again, cause (high risk fetuses more likely to be delivered by C-section) versus effect (surgery increases risk to the fetus) remains epidemiologically obscure. The medical indications for C-section necessarily entail broad obstetrician discretion because of the need to: (1) Balance any conflicting medical conditions of mother versus fetus; and (2) balance C-section against any other competing clinical considerations or external constraints (for example, availability of operating room, personnel, and/or blood).

Furthermore, C-sections receive higher reimbursement than vaginal deliveries (typically about 50 percent more). Patient cost sharing may differ, depending upon insurance coverage. Insurance experiments suggest that higher cost sharing causes patients to consume less health care,[546] but that patients distinguish poorly between necessary and unnecessary services. The pervasive use of cesarean births carries economic impacts because C-sections are more expensive than vaginal deliveries and may be accompanied by adverse outcomes and complications which similarly have substantial cost implications.[547]

For these reasons, we are considering including the electronic version of PC–02 (NQF #0471e) in the eCQM measure set to enable hospitals to track C-sections and reduce unnecessary instances of C-sections.

(2) Overview of Measure

The Joint Commission is the steward of the PC–02 measure, which assesses the rate of nulliparous women with a normal-term, singleton fetus in the vertex position (NTSV) undergoing C-section.[548] Nulliparous women are those who have never given birth. They have a lower risk during vaginal birth than do women who have undergone a previous C-section.[549] [550] Full-term births have better outcomes than preterm births. Vertex presentations carry less risk than breach or transverse presentations.[551] However, this population still includes some patients with medical indications for elective C-section (for example, dystocia, chorioamnionitis, pelvic deformity, preeclampsia, fetal distress, prolapsed cord, placenta previa, abnormal lie, uterine rupture, macrosomia).[552] While the chart-abstracted and eCQM versions of PC–02 do not exclude those medical indications, extensive testing of the chart-abstracted version of the measure has shown that excluding them does not significantly increase a hospital's adjusted C-section rate, partially because the majority of these indications are rare in the NTSV population.[553]

1990–2013. *National Vital Statistics Reports,* 63(6): 1–16.

[533] Martin, J.A., Hamilton, B.E., Osterman, M.J.K., Driscoll, A.K., Drake, P. (2018). Births: Final Data for 2016. *National Vital Statistics Reports,* 67(1): 1–55.

[534] Kozhimannil, K.B., Law, M.R. & Virnig, B.A. (2013). Cesarean delivery rates vary tenfold among US hospitals; reducing variation may address quality and cost issues. *Health Affairs,* 32(3): 527–35.

[535] National Collaborating Centre for Women's and Children's Health. (2011). Caesarean Section: NICE Clinical Guideline (commissioned by the United Kingdom National Institute for Health and Clinical Excellence).

[536] American College of Obstetricians and Gynecologists, Society for Maternal-Fetal Medicine. (2014). Safe prevention of the primary cesarean delivery. *American Journal of Obstetrics and Gynecology,* 210(3): 179–93.

[537] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. *Plos Med,* 15(1): e1002494.

[538] American College of Obstetricians and Gynecologists, Society for Maternal-Fetal Medicine. (2014). Safe prevention of the primary cesarean delivery. *American Journal of Obstetrics and Gynecology,* 210(3): 179–93.

[539] National Collaborating Centre for Women's and Children's Health. (2011). Caesarean Section: NICE Clinical Guideline (commissioned by the United Kingdom National Institute for Health and Clinical Excellence).

[540] American College of Obstetricians and Gynecologists, Society for Maternal-Fetal Medicine. (2014). Safe prevention of the primary cesarean delivery. *American Journal of Obstetrics and Gynecology,* 210(3): 179–93.

[541] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. *Plos Med,* 15(1): e1002494.

[542] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. *Plos Med,* 15(1): e1002494.

[543] American College of Obstetricians and Gynecologists, Society for Maternal-Fetal Medicine. (2014). Safe prevention of the primary cesarean delivery. *American Journal of Obstetrics and Gynecology,* 210(3): 179–93.

[544] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. *Plos Med,* 15(1): e1002494.

[545] American College of Obstetricians and Gynecologists, Society for Maternal-Fetal Medicine. (2014). Safe prevention of the primary cesarean delivery. *American Journal of Obstetrics and Gynecology,* 210(3): 179–93.

[546] Aron-Dine, A., Einav, L. & Finkelstein, A. (2013). The RAND Health Insurance Experiment, Three Decades Later. *The Journal of Economic Perspectives,* 27(1): 197–222.

[547] Kozhimannil, K.B., Law, M.R. & Virnig, B.A. (2013). Cesarean delivery rates vary tenfold among US hospitals; reducing variation may address quality and cost issues. *Health Affairs,* 32(3): 527–35.

[548] National Quality Forum, Quality Measure PC–02 (Cesarean Birth). Available at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=291&print=1&entityTypeID=1.*

[549] American College of Obstetricians and Gynecologists, Society for Maternal-Fetal Medicine. (2014). Safe prevention of the primary cesarean delivery. *American Journal of Obstetrics and Gynecology,* 210(3): 179–93.

[550] National Quality Forum, *Perinatal and Reproductive Health 2015–2016 Final Report.* Available at: *http://www.qualityforum.org/Publications/2016/12/Perinatal_and_Reproductive_Health_2015-2016_Final_Report.aspx.*

[551] American College of Obstetricians and Gynecologists, Society for Maternal-Fetal Medicine. (2014). Safe prevention of the primary cesarean delivery. *American Journal of Obstetrics and Gynecology,* 210(3): 179–93.

[552] Mylonas, I. & Friese, K. (2015). Indications for and Risks of Elective Cesarean Section. *Deutsches Arzteblatt International,* 112(29–30): 489–95.

[553] Centers for Medicare & Medicaid Services. (2015). Cesarean Birth (PC–02) Measure Public Comment Summary. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-*

Determining the NTSV C-section rate permits a hospital to compare its outcomes to other hospitals while focusing only on a lower-risk population. NQF has endorsed the chart-based form of this measure as a voluntary consensus standard since 2008.[554] NQF stated that decreasing the rate of unnecessary C-sections ''will result in increased patient safety, a substantial decrease in maternal and neonatal morbidity and substantial savings in health care costs.'' [555] Reducing the number of NSTV deliveries by C-section would also reduce the rate of repeat cesarean births.[556] We acknowledge that there are instances where C-sections are medically indicated, and we emphasize that this measure is not intended to discourage practitioners from performing C-sections when they are medically indicated. We believe that assessing the rate of NTSV C-sections may ultimately reduce the occurrence of non-medically indicated C-sections. We have encouraged hospitals whose measure rates are higher than rates at other hospitals to explore and evaluate differences in the medical and nursing management of women in labor.[557] Further, including this measure could help ensure that the Hospital IQR Program includes measures which are applicable to rural hospitals. The Rural Health Workgroup of the NQF's Measure Applications Partnership also identified the chart-abstracted version of PC–02 as a measure that holds particular relevance for rural hospitals, noting how important it is to focus on best practices in obstetric care in rural areas.[558]

The PC–02 eCQM was included in a publicly available document entitled ''List of Measures Under Consideration for December 1, 2018.'' [559] The MAP Coordinating Committee voted to conditionally support the PC–02 eCQM, citing the failure of the eCQM version of the measure to attain endorsement by the NQF as an area of concern.[560] The Coordinating Committee encouraged The Joint Commission to resubmit the eCQM version of PC–02 to the NQF for endorsement with additional clarifying data that has been collected since the previous attempt to attain endorsement. The MAP's Final Report of February 15, 2019, conditionally supports the PC–02 eCQM for rulemaking pending NQF evaluation and endorsement.[561] The MAP suggested feasibility testing, consultation with multiple stakeholders, and examination of unintended consequences.

(3) Data Sources

Hospitals would provide data for this measure from their EHRs. Incorporating this eCQM would align with our goal to encourage greater use of EHR data for quality measurement.

(4) Measure Calculation

This measure assesses the rate of nulliparous women with a term, singleton baby in a vertex position delivered by cesarean birth. As the measure steward for both the chart-abstracted version of PC–02 (NQF #0471) and the eCQM version (NQF #0471e), The Joint Commission publishes a detailed methodology for its calculation.[562]

The measure's denominator consists of the number of nulliparous women with a singleton, vertex fetus at ≥37 weeks of gestation who deliver a liveborn infant. Its numerator consists of the subset delivering by C-section. The numerator includes women delivering by planned C-section due to obstetric indications and for other reasons.[563] This measure excludes patients with abnormal presentations or single stillbirth during the encounter, or patients with multiple gestations recorded less than or equal to 42 weeks prior to the end of the encounter.

The cohort consists of all patients in the denominator: Nulliparous women with a singleton, vertex fetus at ≥37 weeks of gestation who deliver a liveborn infant. The cohort includes all pertinent patients regardless of payer (for example, Medicare, Medicaid, other public programs, private insurance, self-pay, charity care) or admission source (for example, home, emergency department, nursing home, hospice, another hospital, law enforcement).[564] The cohort for a region, hospital, and practitioner may differ from the national rate because of higher medical indications for C-section.

(5) Outcome

The outcome of interest is the number of C-sections to nulliparous women with a term, singleton baby in a vertex position divided by all deliveries to nulliparous women with a term, singleton baby in a vertex position.[565]

This measure is not risk adjusted. The Joint Commission decided to exclude risk-adjustment from this measure based on careful consideration of a Technical Advisory Panel's recommendations and data that indicated the results adjusted by age were sensitive to low sample sizes and applying age as a risk factor only marginally impacted the outcome.[566] The Joint Commission removed all risk adjustments from this measure, effective with discharges beginning July 1, 2016.[567]

Assessment-Instruments/MMS/Downloads/PC-02-Public-Comment-Summary-Memo.pdf. The PC–02 eCQM cannot capture all possible medical indications. Thus, PC–02 does not equate to elective C-section for non-medical reasons.

[554] National Quality Forum, Quality Measure PC–02 (Cesarean Birth). Available at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=291&print=1&entityTypeID=1.*

[555] National Quality Forum (NQF), Perinatal and Reproductive Health Project. NQF #0471 PC–02 Cesarean Section: Measure Submission and Evaluation Worksheet 5.0. October 24, 2008. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69252.*

[556] Curtin, S.C., Gregory, K.D., Korst, L.M., & Uddin, S.F. (2015). Maternal Morbidity for Vaginal and Cesarean Deliveries, According to Previous Cesarean History: New Data From the Birth Certificate, 2013. *National Vital Statistics Reports,* 64(4): 1–13.

[557] Centers for Medicare & Medicaid Services. (2015). Cesarean Birth (PC–02) Measure Public Comment Summary. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/PC-02-Public-Comment-Summary-Memo.pdf.*

[558] National Quality Forum, Measure Applications Partnership. (2018). *A Core Set of Rural-Relevant Measures and Measuring and Improving Access to Care: 2018 Recommendations from the MAP Rural Health Workgroup.* Available at: *http://www.qualityforum.org/Publications/2018/08/MAP_Rural_Health_Final_Report_-_2018.aspx.*

[559] List of Measures Under Consideration for December 1, 2018. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[560] Measure Applications Partnership, December 2018 NQF MAP Hospital Workgroup Meeting Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[561] National Quality Forum, Measure Applications Partnership, *MAP 2019 Considerations for Implementing Measures in Federal Programs: Hospitals.* Available at: *http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx.*

[562] See, for example, The Joint Commission. Specifications Manual for Joint Commission National Quality Measures, Measure Information Form PC–02. Available at: *https://manual.jointcommission.org/releases/TJC2018A1/MIF0167.html.*

[563] List of Measures Under Consideration for December 1, 2018. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[564] Ibid.

[565] The Joint Commission, Specifications Manual for Joint Commission National Quality Measures, Measure Information Form PC–02. Available at: *https://manual.jointcommission.org/releases/TJC2018A1/MIF0167.html.*

[566] National Quality Forum, (2016) *Perinatal and Reproductive Health 2015–2016 Final Report.* Available at: *http://www.qualityforum.org/Publications/2016/12/Perinatal_and_Reproductive_Health_2015-2016_Final_Report.aspx.*

[567] National Quality Forum, *Perinatal and Reproductive Health 2015–2016 Final Report.* Available at: *http://www.qualityforum.org/Publications/2016/12/Perinatal_and_Reproductive_Health_2015-2016_Final_Report.aspx.*

We are inviting public comment on potential future inclusion of the Cesarean Birth (PC–02) eCQM (NQF #0471e) in the Hospital IQR Program. We are specifically seeking public comment on any unintended consequences that might result from future adoption of this measure, as well as ways to address those potential unintended consequences. We note that we are also considering this measure for potential future inclusion in the Promoting Interoperability Program.

9. Accounting for Social Risk Factors: Update on Confidential Reporting of Stratified Data for Hospital Quality Measures

a. Background

We first sought public comment on potentially publicly reporting Hospital IQR Program measure data stratified by social risk factors in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 57167 through 57168). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), we explained that due to the complexity of interpreting stratified measure data, we would first consider confidentially reporting such data prior to any future public display on the *Hospital Compare* website. We also noted that providing confidential hospital-specific reports (HSRs) would enable us to obtain hospital feedback on reporting options and ensure the information is valid, reliable, and understandable prior to any future public display (82 FR 38404).

In the FY 2018 IPPS/LTCH PPS rulemaking (82 FR 20070 through 20074; 38403 through 38409), we presented and responded to comments on whether to provide hospitals with confidential results of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506) (Pneumonia Readmission measure) and the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (NQF #0468) (Pneumonia Mortality measure) stratified by patient dual eligible status as early as summer of 2018, and described two potential methodologies designed to illuminate potential disparities by calculating outcome measure results stratified by patient dual eligible status (a within-hospital method and an across-hospital method).[568] We selected the two pneumonia measures as the first measures to potentially stratify because pneumonia is a condition that is common in the elderly population and because the results of both measures are publicly reported for a large cohort of hospitals (83 FR 41598).[569] We also explained that the additional information provided by the two disparity methods supplements the overall readmission and mortality measure rates publicly reported on the *Hospital Compare* website by highlighting disparities based on patient dual eligible status (82 FR 38405).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41598), we explained that as a first step, in the interest of simplicity and minimizing confusion for hospitals, we planned to provide hospitals with confidential HSRs containing stratified results of the Pneumonia Readmission measure only, using both disparity methods, during a month-long confidential reporting period in late summer of 2018. We also noted that for the future, we were considering: (1) Expanding our efforts to provide stratified data in confidential HSRs for other measures; (2) including other social risk factors beyond dual eligible status in confidential HSRs; and (3) eventually, making stratified data publicly available on the *Hospital Compare* website (83 FR 41598).

Confidential HSRs containing the results of Pneumonia Readmission measure data using the two disparity methods (disparity results) were made available for hospitals and their QIN–QIOs to download through the QualityNet Secure Portal from August 24 to September 24, 2018. The confidential HSRs also contained additional information to enable a more meaningful comparison and comprehensive assessment of the quality of care for dual eligible patients, including a hospital's overall Pneumonia Readmission measure rate and State and national results for each disparity method. To ensure hospitals and stakeholders would have sufficient information to understand and interpret their disparity results during the confidential reporting period, background materials and educational resources were posted on the QualityNet website, including detailed instructions for interpreting a hospital's HSR and a technical report describing the two disparity methods in detail.[570] We also hosted a National Provider Call and established a monitored email inbox to receive and address questions and comments from hospitals and other stakeholders during the confidential reporting period.[571]

b. Additional Confidential Reporting of Measures Stratified Using Two Disparity Methods

As noted above, we have been considering, among other things, expanding our efforts to provide stratified data using the two disparity methods in confidential HSRs for additional measures. Although our preliminary efforts have focused on the Pneumonia Readmission measure, the two disparity methods previously used can be applied to other outcome measures. We believe that it is important to expand our efforts to provide disparity results for additional outcome measures because we believe that providing the results of both disparity methods alongside a hospital's measure data, as a point of reference, allows for a more meaningful comparison. As mentioned, the disparity results could supplement the overall measure data already publicly reported on the *Hospital Compare* website by providing additional information regarding disparities measured within individual hospitals and across hospitals nationally. The disparity results thus enable a more comprehensive assessment of quality of care for patients with social risk factors and identifies where disparities in health care may exist. This approach also furthers Recommendation 2 of NQF's Disparities Project final report to use and prioritize stratified health equity outcome measures, wherein the two disparity methods were highlighted as exemplary of health equity performance measure alignment such that data collection burden is minimized, measure impact is maximized, and peer group comparisons are enabled.[572] We believe

[568] The Within-Hospital Disparity Method (also referred to as the Dual Eligible Disparity Method for Within-Hospital Comparison) highlights differences in outcomes for dual eligible versus non-dual eligible patients within an individual hospital, while the Dual Eligible Outcome Method (also referred to as the Dual Eligible Outcome Method for Across Hospital Comparison) allows for a comparison of performance in care for dual eligible patients across hospitals.

[569] *Assessing Hospital Disparities for Dual Eligible Patients: Thirty-Day All-Cause Unplanned Readmission Following Pneumonia Hospitalization, Measure Methodology Report for 2018 Confidential Reporting.* Available at: *https://www.qualitynet.org/dcs/ContentServer?cid=%2012287767091038pagename=QnetPublic%2FPage%2FQnetTier3&c=Page.*

[570] These materials, as well as other confidential reporting resources such as Frequently Asked Questions (FAQs), Disparity Methods HSR User Guide, and National Provider Call materials, are available on the confidential reporting pages of the QualityNet website, available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776708906.*

[571] Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776708906.*

[572] National Quality Forum. (2017). *A Roadmap for Promoting Health Equity and Eliminating Disparities: The Four I's for Health Equity.*

hospitals can use their results from the disparity methods to identify and develop strategies to reduce disparities in the quality of care for patients with social risk factors, including targeted improvement efforts to improve health outcomes for all of their patients, those with and without social risk factors (83 FR 41598). As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41599), the two disparity methods do not place any additional collection or reporting burden on hospitals because dual eligible data are readily available in claims data. For additional information on the two disparity methods, we refer readers to the technical report describing the methods in detail,[573] as well as the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407).

In the spring of 2019, we will continue to provide confidential reporting of disparity results for the Pneumonia Readmission measure in the confidential HSRs for claims-based measures that are made available for hospitals to download through the QualityNet Secure Portal as was done in 2018. We are also planning to expand our efforts to apply the two disparity methods to additional outcome measures for confidential reporting in a phased manner. As a next step, in the spring of 2020, we plan to add to the confidential HSRs for claims-based measures the confidential reporting of disparity results for five additional claims-based condition- and procedure-specific readmission measures as follows: (1) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (AMI Readmission measure); (2) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (CABG Readmission measure); (3) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891) (COPD Readmission measure); (4) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization (NQF #0330) (HF Readmission measure); and (5) Hospital-Level 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) (THA/TKA Readmission measure). To simplify and minimize the number of confidential HSRs that hospitals receive, going forward we plan to include hospitals' disparity results in the regular annual confidential HSRs for claims-based measure results that are made available for hospitals to download through the QualityNet Secure Portal each spring, as opposed to a separate confidential HSR for only the confidential reporting of disparity results as was done for the first confidential reporting of disparity results for the Pneumonia Readmission measure in late summer of 2018.

We believe that expanding our efforts by providing disparity results for the six condition- and procedure-specific readmission measures discussed above, while a different set of calculations than those used in the Hospital Readmissions Reduction Program, can complement the stratified methodology used to assess a hospital's performance on these measures for payment penalty scoring purposes under the Hospital Readmissions Reduction Program. To implement the requirements of the 21st Century Cures Act, the Hospital Readmissions Reduction Program developed a stratification methodology to account for social risk factors by which it assigns hospitals into five peer groups based on proportion of dual eligible stays, and assesses hospital performance relative to the performance of hospitals within the same peer group.[574] While this approach is used by the Hospital Readmissions Reduction Program for purposes of payment calculations, the two disparity methods are intended to account for social risk factors by providing additional information that identifies potential disparities in care provided to dual eligible patients within individual hospitals and across hospitals nationally. We believe that providing data from the two disparity methods for the readmission measures complements the payment stratification approach using these measures under the Hospital Readmissions Reduction Program by increasing transparency around, and contributing to an improved understanding of, differences in care on the basis of patient dual eligible status. The two disparity methods and the stratified methodology used by the Hospital Readmissions Reduction Program are all part of CMS' broader efforts to account for social risk factors in quality measurement and value-based purchasing programs. We note that the confidential reporting of disparity results discussed in this section is not driven by a specific quality program, but rather, is intended to supplement already publicly reported measure performance data and is only one part of CMS' overall strategy for accounting for social risk factors. We refer readers to section IV.G.11. of the preamble of this proposed rule for a similar discussion under the Hospital Readmissions Reduction Program. In the future, we also plan to provide confidential reporting of disparity results for additional outcome measures included in other quality programs.

We plan to continue soliciting feedback from hospitals based on their experiences with the confidential disparity methods reporting process, which will allow hospitals to understand their disparity results prior to any potential future public reporting. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41600), we have not yet determined future plans with respect to publicly reporting stratified data, and intend to continue to engage with hospitals and relevant stakeholders about their experiences with and recommendations for the stratification of measure data, and to ensure the reliability of such data before proposing to publicly display stratified measure data in the future. Any proposal to display stratified quality measure data on the *Hospital Compare* website would be made through future rulemaking.

We are inviting public comment on our plans to expand our efforts to apply the disparity methods to additional outcome measures for confidential reporting in a phased manner, specifically for five additional measures (AMI Readmission measure; CABG Readmission measure; COPD Readmission measure; HF Readmission measure; and THA/TKA Readmission measure) starting in spring of 2020, and additional outcome measures after spring of 2020, as discussed above. We refer readers to section IV.G.11. of the preamble of this proposed rule for a similar discussion under the Hospital Readmissions Reduction Program.

Available at: *http://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities__The_Four_I_s_for_Health_Equity.aspx.*

[573] *Assessing Hospital Disparities for Dual Eligible Patients: Thirty-Day All-Cause Unplanned Readmission Following Pneumonia Hospitalization, Measure Methodology Report for 2018 Confidential Reporting.* Available at: *https://www.qualitynet.org/dcs/ContentServer?cid=%201228776709103&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page.*

[574] As required by the 21st Century Cures Act, the Hospital Readmissions Reduction Program implemented a transitional adjustment methodology for dual eligible patients beginning in FY 2019. For additional details on the stratified methodology used in the Hospital Readmissions Reduction Program, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41436 through 41438).

10. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the description above. In accordance with the statute, the FY 2020 payment determination will begin the sixth year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period of time. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at: *http://www.QualityNet.org/.* The technical specifications used for electronic clinical quality measures (eCQMs) are contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). We generally update the measure specifications on an annual basis through the Annual Update, which includes code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and electronic health record (EHR) vendors to use in order to collect and submit data on eCQMs from hospital EHRs. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/.* For example, for the CY 2019 reporting period/FY 2021 payment determination, hospitals would need to submit eCQM data using the May 2018 Annual Update and any applicable addenda. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41602 through 41603), in which we discuss the transition to Clinical Quality Language (CQL) for all eCQM specifications published in CY 2018 for the CY 2019 reporting period/FY 2021 payment determination and subsequent years (beginning with the Annual Update that was published in May 2018 for implementation in CY 2019).

Hospitals must register and submit quality data through the secure portion of the QualityNet website. There are safeguards in place in accordance with the HIPAA Privacy and Security Rules to protect patient information submitted through this website. See 45 CFR parts 160 and 164, subparts A, C and E.

b. Procedural Requirements

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57168). We are not proposing any changes to these procedural requirements in this proposed rule.

c. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. We are not proposing any changes to the data submission requirements for chart-abstracted measures in this proposed rule.

d. Reporting and Submission Requirements for eCQMs

(1) Background

For a discussion of our previously finalized eCQMs and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57161; and 57169 through 57172), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361; 38386 through 38394; 38474 through 38485; and 38487 through 38493), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41567 through 41575; 83 FR 41602 through 41607).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38361), we finalized eCQM reporting and submission requirements such that hospitals are required to report only one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41603 through 41604), we extended the same eCQM reporting and submission requirements, such that hospitals are required to report one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2019 reporting period/FY 2021 payment determination.

In this proposed rule, we are proposing to establish eCQM reporting and submission requirements for the CY 2020 reporting period/FY 2022 payment determination through the CY 2022 reporting period/FY 2024 payment determination, as detailed below.

(2) Proposed Reporting and Submission Requirements for eCQMs for the CY 2020 Reporting Period/FY 2022 Payment Determination

For the CY 2020 reporting period/FY 2022 payment determination, we are proposing to extend the current eCQM reporting and submission requirements, such that hospitals would be required to report one, self-selected calendar quarter of data for four self-selected eCQMs. We believe continuing the same eCQM reporting and submission requirements is appropriate because it offers hospitals reporting flexibility and does not increase the information collection burden on data submitters, allowing them to shift resources to support system upgrades, data mapping, and staff training related to eCQM documentation and reporting.

We also refer readers to section VIII.D.6.d.(1) of the preamble of this proposed rule for a similar proposal in the Promoting Interoperability Programs for the CY 2020 reporting period.

(3) Proposed Reporting and Submission Requirements for eCQMs for the CY 2021 Reporting Period/FY 2023 Payment Determination

For the CY 2021 reporting period/FY 2023 payment determination, we are proposing to extend the same eCQM reporting and submission requirements, such that hospitals would continue to be required to report one, self-selected calendar quarter of data for four self-selected eCQMs for the same reasons as discussed above.

We also refer readers to section VIII.D.6.d.(1) of the preamble of this proposed rule for a similar proposal in the Medicare Promoting Interoperability Program.

(4) Proposed Reporting and Submission Requirements for eCQMs for the CY 2022 Reporting Period/FY 2024 Payment Determination

For the CY 2022 reporting period/FY 2024 payment determination, we are proposing to modify the eCQM reporting and submission requirements, such that hospitals would be required to report one, self-selected calendar quarter of data for: (a) Three self-selected eCQMs, and (b) the proposed Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e), for a total of four eCQMs. We note that the number of calendar quarters of data and total number of eCQMs required would remain the same.

This proposal is being made in conjunction with our proposal in section VIII.A.5.a.(1) of the preamble of this proposed rule, in which we are proposing to adopt the Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) beginning with the CY 2021 reporting period/FY 2023 payment determination. We believe this measure has the potential to reduce preventable mortality and costs associated with other adverse events related to opioid use. As discussed in section VIII.A.5.a.(1) of the preamble of this proposed rule, concurrent opioid or opioid-benzodiazepine prescription use contributes significantly to the overall population's risk of opioid overdose. Currently, however, no measure exists to assess nationwide rates of concurrent prescribing of opioids and benzodiazepines at the hospital-level.

In developing this proposal, we also considered an alternative whereby hospitals would have the option to select one of the two proposed opioids-related eCQMs, the Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) or the Hospital Harm—Opioid-Related Adverse Events eCQM, as their fourth required eCQM. However, such an approach would add complexity to the eCQM reporting requirements, and we believe that the Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) is more closely related to combating the current opioid epidemic, as discussed above and in section VIII.A.5.a. of the preamble of this proposed rule, than the Hospital Harm—Opioid-Related Adverse Events eCQM, which is focused on improved monitoring of patients who receive opioids during hospitalization.

If our proposal to adopt the Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) beginning with the CY 2021 reporting period/FY 2023 payment determination is finalized, we are proposing that while this measure would be available for hospitals to select as one of their four self-selected eCQMs for the CY 2021 reporting period, all hospitals would be required to report this eCQM beginning with the CY 2022 reporting period/FY 2024 payment determination. We believe this measure would provide valuable information on this area of high-risk prescribing to providers, and further our efforts to combat the negative impacts of the opioid crisis. We also believe this proposal is consistent with CMS' goal of incrementally increasing the use of EHR data for quality measurement and is responsive to the feedback of some stakeholders urging a faster transition to full electronic reporting.[575]

We note that this proposal is contingent on finalization of our proposal in section VIII.A.5.a.(1) of the preamble of this proposed rule to adopt the Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e). We also refer readers to section VIII.D.6.d.(2) of the preamble of this proposed rule for a similar proposal by the Medicare Promoting Interoperability Program.

(5) Continuation of Certification Requirements for eCQM Reporting

(A) Requiring Use of 2015 Edition Certification Criteria

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41604 through 41607), to align the Hospital IQR Program with the Promoting Interoperability Program, we finalized a policy to require hospitals to use the 2015 Edition certification criteria for certified EHR technology (CEHRT) for the CY 2019 reporting period/FY 2021 payment determination and subsequent years. We are not proposing any changes to this policy in this proposed rule.

(B) Requiring EHR Technology to be Certified to All Available eCQMs

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38391 through 38393), for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination, we finalized a requirement that EHR technology used for eCQM reporting be certified to all eCQMs, but noted that such certified EHR technology does not need to be recertified each time it is updated to a more recent version of the eCQM electronic specifications.

In this proposed rule, we are proposing to continue the requirement that EHRs be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. The 2015 Edition Base EHR definition (as defined by HHS' Office of the National Coordinator for Health Information Technology (ONC) 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications Final Rule (80 FR 62649 through 62655)) requires certified health IT to have the capability to capture and query information relevant to health care quality,[576] which can be ensured by meeting the clinical quality measure certification criteria to record and export (45 CFR 170.315(c)(1)). The 2015 Edition Base EHR definition does not require certified health IT to meet additional clinical quality measure certification criteria such as to import and calculate (45 CFR 170.315(c)(2)), report (45 CFR 170.315(c)(3)), or filter (45 CFR 170.315(c)(4)).

ONC's Health IT Certification Program is ''agnostic'' to settings and programs, but can support many different use cases and needs.[577] Because the ONC Health IT Certification Program supports multiple program and setting needs, ONC does not include requirements that are specific to CMS programs. CMS may impose more stringent requirements for EHR-based reporting under its programs.

The Hospital IQR and Promoting Interoperability Programs have previously required EHRs to be certified to all available eCQMs used in the programs (that is, individual testing of each eCQM) in order to support flexibility for hospitals when they select the eCQMs on which to report.[578] When EHRs are certified to all available eCQMs in the eCQM measure set, hospitals are able to select and report on those measures that best reflect their

[575] The Office of the National Coordinator for Health Information Technology. (2018). *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs* (Draft for Public Comment). Available at: *https://www.healthit.gov/sites/default/files/page/2018-11/Draft%20Strategy%20on%20Reducing%20Regulatory%20and%20Administrative%20Burden%20Relating.pdf.*

[576] 45 CFR 170.102.

[577] ONC, *2015 Edition Final Rule: Overview of the 2015 Edition Health IT Certification Criteria & ONC Health IT Certification Program Provisions.* Available at: *https://www.healthit.gov/sites/default/files/onc_2015_edition_final_rule_presentation_10-28-15.pdf.*

[578] 82 FR 38391 through 38393; 83 FR 41672.

patient populations and reporting capabilities. In addition to supporting hospital flexibility, we believe the continuation of this requirement promotes more accurate electronic quality reporting by incentivizing EHR and other health IT vendors to test all available eCQMs and to offer reporting modules with certified eCQMs. This requirement would produce greater certainty for hospitals that their EHR systems would be capable of accurately calculating the particular eCQMs they select to report to CMS. We believe this would help reduce burden for hospitals by potentially reducing the frequency of needing to consult with their EHR and other health IT vendors to troubleshoot implementation or reporting issues.

We have continued to hear from hospital stakeholders during a series of provider listening sessions in 2018 that they believe certification is an important part of ensuring successful reporting to CMS. In addition, because this has been the current policy for the Hospital IQR and Promoting Interoperability Programs (82 FR 38391 through 38393; 83 FR 41672), vendors and providers should be familiar with this requirement, and we expect that most providers' EHR systems are already certified to all currently available eCQMs. Since certified EHR technology does not need to be recertified each time it is updated to a more recent version of the eCQM electronic specifications under the Hospital IQR Program (82 FR 38393), there should be no added burden with regard to the currently adopted eCQMs in the eCQM measure set.

We also refer readers to section VIII.D.6.e.(1) of the preamble of this proposed rule for a similar proposal for the Promoting Interoperability Program.

(6) File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements. Under these requirements, hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format as was previously required; (2) may use third parties to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I. Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387). We are not proposing any changes to these requirements for eCQMs in this proposed rule.

(7) Submission Deadlines for eCQM Data

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49709), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57172) for our previously adopted policies to align eCQM data reporting periods and submission deadlines for both the Hospital IQR and Medicare Promoting Interoperability Programs. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we finalized the alignment of the Hospital IQR Program eCQM submission deadline with that of the Medicare Promoting Interoperability Program—the end of two months following the close of the calendar year—for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. We note the submission deadline may be moved to the next business day if it falls on a weekend or federal holiday. We are not proposing any changes to the eCQM submission deadlines in this proposed rule.

e. Data Submission and Reporting Requirements for Hybrid Measures

(1) Background

In section VIII.A.5.b. of the preamble of this proposed rule, we are proposing to adopt the Hybrid HWR measure in the Hospital IQR Program beginning with the FY 2026 payment determination, with 2 years of voluntary reporting prior to that time. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized voluntary reporting of the Hybrid HWR measure for the CY 2018 reporting period. For data submission and reporting requirements under the 2018 Voluntary Reporting Period, we finalized that the 13 core clinical data elements and six linking variables for the Hybrid HWR measure be submitted using the QRDA I file format, and that hospitals voluntarily reporting data for the Hybrid HWR measure could use EHR technology certified to the 2014 Edition, the 2015 Edition, or a combination thereof (82 FR 38394 through 38397). During the 2018 Voluntary Reporting Period, participating hospitals and their health IT vendors reported data on discharges for the January 1, 2018 through June 30, 2018 reporting period by the submission deadline of January 4, 2019, and approximately 80 hospitals submitted data. We expect that hospitals that voluntarily submitted data for this measure will receive confidential hospital-specific reports detailing submission results from the reporting period in early summer of 2019.

(2) Certification and File Format Requirements

In this proposed rule, we are proposing to require that hospitals use EHR technology certified to the 2015 Edition to submit data on the Hybrid HWR measure. This is consistent with our policy finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41604 through 41607), which requires use of the 2015 Edition certification criteria for CEHRT when reporting eCQMs beginning with the CY 2019 reporting period/FY 2021 payment determination.

In addition, we are proposing that the core clinical data elements and linking variables identified in hybrid measure specifications, for example as described in section VIII.A.5.b. of the preamble of this proposed rule, be submitted using the QRDA I file format. In order to ensure that the data have been appropriately connected to the encounter, the core clinical data elements specified for risk adjustment need to be captured in relation to the start of an inpatient encounter. The QRDA I standard enables the creation of an individual patient-level quality report that contains quality data for one patient for one or more quality measures. Based on the experience of the CY 2018 Voluntary Reporting Period, the use of the QRDA I file format is feasible. In addition, hospitals and health IT vendors have been using the QRDA I file format for eCQM reporting for several years.

For details on the implementation guidance provided for the Hybrid HWR measure 2018 Voluntary Reporting Period, we refer readers to the 2018 CMS QRDA I Implementation Guide for Hospital Quality Reporting and the 2018 CMS QRDA I Schematrons and Sample Files for HQR, available on the eCQI Resource Center website.[579] If our proposal to adopt the Hybrid HWR measure is finalized, updated implementation guidance, schematrons, and sample files will become available on the eCQI Resource Center website.

As with eCQM reporting, we also encourage all hospitals and their health IT vendors to submit QRDA I files early,

[579] The Electronic Clinical Quality Improvement (eCQI) Resource Center. Eligible Hospitals/Critical Access Hospital eCQMs. Available at: *https://ecqi.healthit.gov/eligible-hospital/critical-access-hospital-ecqms.*

and to use one of the pre-submission testing tools for electronic reporting, such as the CMS Pre-Submission Validation Application (PSVA) tool (81 FR 57113), to allow additional time for testing and to make sure all required data files are successfully submitted by the deadline. The PSVA tool can be downloaded from the Secure File Transfer (SFT) section of the QualityNet Secure Portal at: *https://cportal.qualitynet.org/QNet/pgm_select.jsp.*

(3) Additional Submission Requirements

In this proposed rule, we are proposing to allow hospitals to meet the hybrid measure reporting and submission requirements by submitting any combination of data via QRDA I files, zero denominator declarations, and/or case threshold exemptions. We recognize the challenges associated with electronic reporting and encourage hospitals of all sizes to work with their vendors to achieve electronic capture and reporting of data necessary for hybrid measure reporting. We also acknowledge that there are situations in which a hospital may be prepared for electronic reporting, but may not have data to report on a particular measure. For example, hospitals with small patient populations may not have sufficient patient population to report on specific measures, such that those hospitals may find it necessary to utilize a zero denominator declaration and/or case threshold exemption. In addition, there may be situations in which case number thresholds are appropriate, given the burden on hospitals that very seldom have the types of cases addressed by certain measures.

In this proposed rule, we are proposing to apply similar zero denominator declaration and case threshold exemption policies to hybrid measure reporting as we allow for eCQM reporting. In other words, for a zero denominator declaration, if a hospital's EHR is otherwise capable of reporting hybrid measure data, but the hospital does not have patients that meet the denominator criteria of that hybrid measure, the hospital may submit a zero in the denominator for that measure. Submission of a zero in the denominator for a hybrid measure would count as a successful submission for that hybrid measure for the Hospital IQR Program. In addition, for the case threshold exemption, hospitals that have five or fewer inpatient discharges per quarter or twenty or fewer inpatient discharges per year as defined by a hybrid measure's denominator population, would be exempted from reporting on that hybrid measure. Hospitals can submit zero denominator declarations or case threshold exemptions by logging into the QualityNet Secure Portal and completing the Denominator Declaration screen.

(4) Submission Deadlines for Hybrid Measures

We are proposing that hospitals must submit the core clinical data elements and linking variables within three months following the end of the applicable reporting period (submissions would be required no later than the first business day three months following the end of the reporting period) for hybrid measures in the Hospital IQR Program.

As discussed earlier in this proposed rule, we are proposing that the first voluntary reporting period would run from July 1, 2021 through June 30, 2022. Under this proposal, for example, hospitals would be required to submit the core clinical data elements and linking variable data no later than Friday, September, 30, 2022, which is the first business day three months following the end of the reporting period. Similarly, for the July 1, 2022 through June 30, 2023 voluntary reporting period, for example, the submission deadline would be Monday, October 2, 2023. If our proposal to adopt the Hybrid HWR measure is finalized, this submission deadline would apply to all reporting periods for which data are submitted.

f. Sampling and Case Thresholds for Chart-Abstracted Measures

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49709) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. We are not proposing any changes to our sampling and case threshold policies in this proposed rule.

g. HCAHPS Administration and Submission Requirements

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS submission requirements. We also refer hospitals and HCAHPS Survey vendors to the official HCAHPS website at: *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59140 through 59149), we updated the HCAHPS Survey by removing the Communication About Pain questions effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years, and finalizing a policy of not publicly reporting data regarding these questions. We are not proposing any changes to the HCAHPS Survey or its administration and submission requirements in this proposed rule.

h. Data Submission Requirements for Structural Measures

There are no remaining structural measures in the Hospital IQR Program.

i. Data Submission and Reporting Requirements for CDC NHSN HAI Measures

For details on the data submission and reporting requirements for Healthcare-Associated Infection (HAI) measures reported via the CDC's National Healthcare Safety Network (NHSN), we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet website at: *http://www.QualityNet.org/.* We are not proposing any changes to those requirements in this proposed rule.

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41547 through 41553), in which we finalized the removal of five of these measures (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI) from the Hospital IQR Program. As a result, hospitals will not be required to submit any data for those measures under the Hospital IQR Program following their removal beginning with the CY 2020 reporting period/FY 2022 payment determination. However, the five CDC NHSN HAI measures will be included in the HAC Reduction and Hospital VBP Programs and reported via the CDC NHSN portal (83 FR 41474 through 41477; 83 FR 41449 through 41452). Lastly, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492) as well as sections IV.I.6. and 7. and

IV.H.5.e. of the preamble of this proposed rule for more information and proposals regarding NHSN HAI measure data collection and validation under the HAC Reduction Program and use in the HAC Reduction and Hospital VBP Programs. We further note that the HCP measure remains in the Hospital IQR Program and will continue to be reported via NHSN.

11. Validation of Hospital IQR Program Data

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403) for detailed information on chart-abstracted and eCQM validation processes and previous updates to these processes for the Hospital IQR Program.

In this proposed rule, we are not proposing any changes to the existing processes for validation of chart-abstracted and eCQM measure data. We note that if our proposal to adopt the Hybrid HWR measure is finalized, we intend to propose a validation process for core clinical data elements in future rulemaking.

12. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously adopted details on DACA requirements. We are not proposing any changes to the DACA requirements in this proposed rule.

13. Public Display Requirements

We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49712 through 49713), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* website at: *http://www.medicare.gov/hospitalcompare,* but on occasion are reported on other CMS websites such as: *https://data.medicare.gov.* We are not proposing any changes to the public display requirements in this proposed rule.

14. Reconsideration and Appeal Procedures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. We are not proposing any changes to the reconsideration and appeals procedures in this proposed rule.

15. Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 through 57182), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38409 through 38411), and 42 CFR 412.140(c)(2) for details on the current Hospital IQR Program ECE policy. We also refer readers to the QualityNet website at: *http://www.QualityNet.org/* for our current requirements for submission of a request for an exception. We are not proposing any changes to the ECE policy in this proposed rule.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

Section 1866(k) of the Act establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs'') that specifically applies to PCHs that meet the requirements under 42 CFR 412.23(f). Section 1866(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, a PCH must submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such fiscal year.

The PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program strives to put patients first by ensuring they, along with their clinicians, are empowered to make decisions about their own health care using data-driven insights that are increasingly aligned with meaningful quality measures. To this end, we support technology that reduces burden and allows clinicians to focus on providing high quality health care to their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when participating in CMS programs. In combination with other efforts across the Department of Health and Human Services (HHS), we believe the PCHQR Program incentivizes PCHs to improve their health care quality and value, while giving patients the tools and information needed to make the best decisions.

For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38411 through 38425); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41624); and the CY 2019 OPPS/ASC final rule with comment period (83 FR 59149 through 59154).

In this proposed rule, we are proposing several new policies for the PCHQR Program. We developed these proposals after conducting an overall review of the program under our new Meaningful Measures Initiative, which is discussed in more detail in I.A.2. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148) and this FY 2020 proposed rule. The proposals reflect our efforts to ensure that the PCHQR Program measure set continues to promote improved health outcomes for our beneficiaries. The proposals also reflect our efforts to improve the usefulness of the data that we publicly report in the PCHQR Program.

2. Proposed Refinement of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166): Removal of the Pain Management Questions

a. Background

The HCAHPS Survey (NQF #0166) (OMB Control Number 0938–0981) is the first national, standardized, publicly reported survey of patients' experience of hospital care and asks discharged patients 32 questions about their recent

hospital stay. In May 2005, the HCAHPS Survey was endorsed for the first time by the National Quality Forum (NQF). The HCAHPS Survey is available in English, Spanish, Chinese, Russian, Vietnamese, and Portuguese versions. The HCAHPS Survey, along with its protocols for sampling, data collection and coding, and file submission, can be found in the current HCAHPS *Quality Assurance Guidelines,* which is available on the official HCAHPS website at: *http://www.hcahpsonline.org/en/quality-assurance/.*

We adopted the HCAHPS Survey into the PCHQR Program beginning with the FY 2016 program year in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50844 through 50845); we refer readers to this final rule for a detailed discussion of the survey. Further, we finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49722) that we would begin publicly reporting this measure in the PCHQR Program in CY 2016. For HCAHPS Survey data reported in years prior to CY 2018, we refer readers to: *http://hcahpsonline.org/en/summary-analyses/.*

In this proposed rule, we are proposing to adopt a substantive change to the HCAHPS Survey by removing the three Pain Management questions beginning with October 1, 2019 discharges, as described below.

The patients treated by the 11 PPS-exempt cancer hospitals eligible to participate in the PCHQR Program have been diagnosed with cancer, which frequently causes substantial pain. Cancer treatment also frequently involves surgery, chemotherapy, and/or radiation therapy, all of which can also cause substantial pain beyond that experienced by the general Medicare population.[580] Pain management is therefore an important safeguard against the unintended consequences of appropriate clinical care in these patients.[581]

The version of the HCAHPS Survey currently implemented in the PCHQR Program includes three Pain Management questions, Q12, Q13, and Q14. The questions are as follows:

12. During this hospital stay, did you need medicine for pain?

1 ☐ Yes

2 ☐ No → If No, Go to Question 15

13. During this hospital stay, how often was your pain well controlled?

1 ☐ Never

2 ☐ Sometimes

3 ☐ Usually

4 ☐ Always

14. During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?

1 ☐ Never

2 ☐ Sometimes

3 ☐ Usually

4 ☐ Always

The pain management questions that the PCHQR Program currently uses were previously also adopted as part of the HCAHPS survey used by the Hospital IQR Program (71 FR 68202 through 68204) and the Hospital VBP Program (76 FR 26510), but the questions have been removed from the survey in both of those programs.

Specifically, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79862), we noted that that we had received feedback that some stakeholders were concerned about the Pain Management dimension questions being used in a program, including the Hospital VBP Program, where there was any link between scoring well on the questions and higher hospital payments (81 FR 79856). Some stakeholders also stated that they believed that the linkage of the pain management questions to the Hospital VBP Program payment incentives created pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the pain management dimension. We also noted that many factors outside of CMS control could contribute to a perception of a link between the questions and opioid prescribing practices, including misuse of the survey (such as using it for outpatient emergency room care instead of inpatient care, or using it for determining physician performance) and failure to recognize that the HCAHPS survey excludes certain populations from the sampling frame (such as those with a primary substance use disorder diagnosis).

We stated that we had heard that some hospitals have identified patient experience as a potential source of competitive advantage, and that some hospitals may be disaggregating their raw HCAHPS data to compare, assess, and incentivize individual physicians, nurses and other hospital staff. We further stated that some hospitals may be using the HCAHPS survey to assess their emergency and outpatient departments. We stated that the HCAHPS survey was never intended to be used in any of these ways.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79859 through 79860), we further noted that numerous commenters had offered support for the development of modified questions regarding pain management for the HCAHPS Survey and that some commenters expressed support for modified pain management questions that focused on effective communication with patients about pain management-related issues. In response, we stated we would follow our standard survey development processes, which include drafting alternative questions, cognitive interviews and focus group evaluation, field testing, statistical analysis, stakeholder input, the Paperwork Reduction Act, and NQF endorsement (81 FR 79856).

We continue to believe that pain control is an appropriate part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers. It is important to note that the HCAHPS Survey does not specify any particular type of pain control method. In addition, appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, and proper prescription practices. However, due to some potential confusion about the appropriate use of the Pain Management dimension questions in the Hospital VBP Program and the public health concern about the ongoing prescription opioid overdose epidemic, in an abundance of caution, we finalized removal of the Pain Management dimension of the HCAHPS Survey in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain of the Hospital VBP Program beginning with the FY 2018 program year (81 FR 79862).

Subsequently, out of an abundance of caution and in the face of a nationwide epidemic of opioid over-prescription, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 through 38342), we finalized a refinement to the HCAHPS Survey measure as used in the Hospital IQR Program by removing the same pain management questions.

b. Proposal To Refine the HCAHPS Survey by Removing the Existing Pain Management Questions

We are proposing to refine the HCAHPS Survey used in the PCHQR Program by removing the three Pain Management questions beginning with October 1, 2019 discharges. As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR

[580] American Cancer Society. ''*Cancer Pain.*'' Available at: *https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/pain.html.*

[581] Mayo Clinic. ''*Cancer Pain: Relief is Possible.*'' Available at: *https://www.mayoclinic.org/diseases-conditions/cancer/in-depth/cancer-pain/art-20045118.*

59141), some hospitals have identified patient experience of care as a potential source of competitive advantage, and stakeholders have also informed CMS that some hospitals may be disaggregating their raw HCAHPS Survey data to compare, assess, and incentivize individual physicians, nurses, and other hospital staff. While this issue was raised in regard to acute care facilities, we are concerned that similar activity might be occurring in PCHs because the incentives to improve patient experience exist across care settings.

We are also concerned about potential confusion about the appropriate use of the pain management questions in the PCHQR Program, given the public health concern about the ongoing prescription opioid overdose epidemic, and believe that removing the pain management questions would eliminate any such potential misuse. We note that the HCAHPS *Quality Assurance Guidelines,*[582] which set forth current survey administration protocols, strongly discourage the unofficial use of HCAHPS scores for comparisons within hospitals, such as for comparisons of particular wards, floors, and individual staff hospital members.

While we recognize the importance of being able to provide performance results within the context of pain management for cancer patients, we also note that pain items in generic patient experience surveys (for example, HCAHPS) have limitations when implemented. As noted above, many factors outside the control of CMS quality program requirements may contribute to the perception of a link between the pain management questions and opioid prescribing practices, including misuse of the HCAHPS Survey (for example, using it for outpatient emergency room care instead of inpatient care, or using it for determining individual physician performance), and failure to recognize that the HCAHPS Survey excludes certain populations from the sampling frame (such as those with a primary substance use disorder diagnosis). Further, in its draft final report, the President's Commission on Combatting Drug Addiction and the Opioid Crisis recommended removal of the HCAHPS Pain Management questions in order to ensure providers are not incentivized to offer opioids to raise their HCAHPS Survey score.[583] We believe that all of these issues support the removal of the pain management questions in the HCAHPS survey used by PCHs.

We also believe that the removal of the questions will promote programmatic alignment with both the Hospital IQR Program and the Hospital VBP Program. Accordingly, we are proposing to remove the Pain Management questions from the version of the HCAHPS Survey currently implemented in the PCHQR Program, beginning with the October 1, 2019 discharges. If finalized as proposed, this would result in the reduction of the number of HCAHPS Survey questions from 32 to 29. We note that this proposed change would not impact how scores are calculated for the remainder of the survey and would not have a significant effect on the reliability of the HCAHPS Survey instrument as a whole.

We also are proposing to not publicly report the data collected on the Pain Management questions beginning with October 2018 discharges in order to address the potential misunderstanding associated with these questions as soon as possible. While the data will not be publicly reported, we still plan to provide performance results to PCHs in confidential preview reports upon the availability of four quarters of CY 2018 data, as early as July 2019.

3. Measure Retention and Removal Factors for the PCHQR Program

a. Measure Retention Factors

We generally retain measures from the previous year's PCHQR Program measure set for subsequent years' measure sets, except when we specifically propose to remove or replace a measure. We have also recognized that there are times when measures may meet one or more of the outlined criteria for removal from the program but continue to bring value to the program. Therefore, we adopted the following factors for consideration in determining whether to retain a measure in the PCHQR Program, which also are based on factors established in the Hospital IQR Program (81 FR 57182 through 57183):

- Measure aligns with other CMS and HHS policy goals;
- Measure aligns with other CMS programs, including other quality reporting programs; and
- Measure supports efforts to move PCHs towards reporting electronic measures.

We are not proposing any changes to these measure retention factors in this proposed rule.

b. Measure Removal Factors

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41611), we discussed our existing measure removal factors for the PCHQR Program.[584] We note that these factors are based on factors adopted for the Hospital IQR Program (81 FR 57182 through 57183; 83 FR 41540 through 41544). We also adopted a new measure removal factor, for a total of eight measure removal factors:

- Factor 1. Measure performance among PCHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (that is, ''topped-out'' measures): Statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤0.10;
- Factor 2. A measure does not align with current clinical guidelines or practice;
- Factor 3. The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 4. Performance or improvement on a measure does not result in better patient outcomes;
- Factor 5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm;
- Factor 7. It is not feasible to implement the measure specifications; and
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

We are not proposing any changes to these measure removal factors in this proposed rule.

4. Proposed Removal of the Web-Based Structural Measure: External Beam Radiotherapy (EBRT) for Bone Metastases From the PCHQR Program Beginning With the FY 2022 Program Year

In this proposed rule, we are proposing to remove the External Beam

[582] HCAHPS Quality Assurance Guidelines (v.13.0), available at: *http://www.hcahpsonline.org/en/quality-assurance/.*

[583] President's Commission on Combating Drug Addiction and the Opioid Crisis draft report, available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf.*

[584] We note that we previously referred to these factors as ''criteria'' (for example, 81 FR 57182 through 57183); we now use the term ''factors'' to align the PCHQR Program terminology with the terminology we use in other CMS quality reporting and pay for performance value-based purchasing programs.

Radiotherapy (EBRT) for Bone Metastases (formerly NQF #1822) [585] measure from the PCHQR Program beginning with the FY 2022 program year, based on removal Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program.

a. Background

We adopted the EBRT measure beginning with the FY 2017 program year (October 1, 2015) in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50279). The EBRT measure reports the percentage of patients, regardless of age, with a diagnosis of painful bone metastases and no history of previous radiation who receive EBRT with an acceptable fractionation scheme as defined by the guideline.

When the EBRT measure was adopted into the PCHQR Program, it initially used ''radiation planning'' current procedural terminology (CPT) codes that were billable at the physician level. After finalizing the measure, we learned that at least one of the 11 PCHs did not have access to physician billing data, making reporting complete data on this measure unduly burdensome and difficult. To address this issue, beginning in March 2016, the measure was updated in the PCHQR Program to enable the use of ''radiation delivery'' CPT codes, which are billable at the hospital level.[586]

b. Analysis of Measure Use

After implementation of the updated EBRT measure in the PCHQR Program, the measure steward conducted testing of data collection of the updated measure in the outpatient setting and discovered that there are new and significant concerns regarding the revised ''radiation delivery'' CPT coding used to report the EBRT measure. Although this testing was done in the outpatient setting, we believe that the issues with the measure that were identified in the outpatient setting similarly affect the inpatient cancer hospital community, as PCHs need to take the same steps as hospital outpatient departments (HOPDs) to report the measure using ''radiation delivery'' CPT codes. In particular, the measure steward has observed that implementing the updated measure in the outpatient setting has proven to be very burdensome on hospitals. The use of ''radiation delivery'' CPT codes requires more complicated measure exclusions to be used because the change to ''radiation delivery'' CPT codes caused the administration of EBRT to different anatomic sites to be considered separate cases for this measure. Because there is no way to determine the different anatomic sites until detailed review of the patient's record is complete, sampling has become a significant concern, and confounded the task of determining which sites should be included or excluded from the measure denominator. In addition, hospitals have difficulty determining if sample size requirements for the measure are being met. As a result, we believe that the complexity of reporting this measure places substantial administrative burden on hospitals.

We also note that the measure lost NQF endorsement in 2018 and that the measure steward is no longer maintaining the measure or seeking NQF re-endorsement. As a result, especially because the steward is no longer maintaining the measure, we no longer believe that we can ensure that the measure is in line with clinical guidelines and standards, which further diminishes the value of the measure.

c. Summary

Ultimately, we believe the burden associated with the measure outweighs the value of its inclusion in the PCHQR Program. We are proposing, under removal Factor 8, to remove the EBRT measure from the PCHQR Program beginning with the FY 2022 program year.

5. Proposed New Quality Measure Beginning With the FY 2022 Program Year

a. Considerations in the Selection of Quality Measures

Under current policy, we take many principles into consideration when developing and selecting measures for the PCHQR Program, and many of these principles are modeled on those we use for measure development and selection under the Hospital IQR Program. In section I.A.2. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), we also discuss our Meaningful Measures Initiative and its relation to how we will assess and select quality measures for the PCHQR Program.

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Section 1866(k)(3)(B) of the Act provides an exception under which, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

After considering these principles for measure selection in the PCHQR Program, in this proposed rule, we are proposing to adopt one new measure beginning with the FY 2022 program year, as described below.

b. Proposed New Quality Measure Beginning With the FY 2022 Program Year: Surgical Treatment Complications for Localized Prostate Cancer

We are proposing to adopt the Surgical Treatment Complications for Localized Prostate Cancer measure for the FY 2022 program year and subsequent years.

(1) Background

Prostate cancer is the most common non-dermatologic malignancy among men in the United States, with an estimated 180,000 new cases/year.[587] Approximately 80 percent of patients are diagnosed with localized disease and therefore may be eligible for prostate directed therapy.[588] This could involve surgical removal of the prostate, radiation therapy, or both. The majority of patients who undergo prostate-directed therapy survive, but these treatments can have serious and potentially longstanding adverse effects, including incontinence, urinary tract obstruction, hydronephrosis, erectile dysfunction, urinary fistula formation, hematuria, cystitis, bowel fistula, proctitis/colitis, bowel bleeding, diarrhea, rectal/anal fissure, abscess, stricture, incision hernia, infection, or others.[589] [590] Patients consistently report

[585] This measure was initially endorsed by NQF, with corresponding measure number 1822. This measure lost its NQF endorsement in March 2018. National Quality Forum Cancer Project Final Report—Spring 2018. Available at: *http://www.qualityforum.org/Publications/2018/08/Cancer_Final_Report_-_Spring_2018_Cycle.aspx.*

[586] 2018 EBRT Measure Information Form. Retrieved from: *https://www.qualitynet.org/dcs/ContentServer?cid=1228774479863&pagename=QnetPublic%2FPage%2FQnetTier4&c=Page.*

[587] Siegel RL, Miller KD, Jemal A. Cancer statistics, 2016. *CA: a cancer journal for clinicians.* 2016;66(1):7–30.

[588] Ibid.

[589] Bekelman JE, Mitra N, Efstathiou J, et al. Outcomes after intensity-modulated versus conformal radiotherapy in older men with nonmetastatic prostate cancer. *International journal of radiation oncology, biology, physics.* 2011;81(4):e325–334.

[590] Potosky AL, Warren JL, Riedel ER, Klabunde CN, Earle CC, Begg CB. Measuring complications of

Continued

that these adverse effects, which are patient-centered outcomes, can have a significant detrimental impact on their quality of life.[591] [592]

Clinical trials and population-based data have been used to determine whether different prostate-directed treatments result in different patient-centered outcomes. These studies have evaluated a range of prostate-directed treatments, including open radical prostatectomy, robot-assisted radical prostatectomy, minimally invasive radical prostatectomy, brachytherapy, external beam radiation therapy, conformal radiation therapy, intensity modulated radiation therapy (IMRT), and proton therapy, and have demonstrated that some treatments are associated with inferior patient-centered outcomes when compared to others. A number of these studies used Medicare claims after therapy for prostate cancer to identify specific outcomes.[593] [594] [595] Very few studies have explored whether the patient-centered outcomes experienced after prostate-directed therapy vary by treating facility. However, studies of other cancers have demonstrated that outcomes can vary by treating facility. For example, operative mortality after major cancer surgery varies inversely with hospital volume.[596]

In recognition of the potential impact of this variation, the Surgical Treatment Complications for Localized Prostate Cancer measure was developed. This measure is based on the *Localized Prostate Cancer Standard Set* (the Standard Set) developed by the International Consortium for Health Outcome Measurement (ICHOM).[597] The Standard Set is a conceptual framework that is supported by a rigorous, evidence-based consensus approach to identify the outcomes that matter most to prostate cancer patients. The Localized Prostate Cancer Standard Set recommends key outcomes that should be measured to improve the lives of patients with localized prostate cancer. We believe that this measure is in line with the Standard Set framework, which recommends measuring complications of prostate-directed surgical treatments. We believe the Surgical Treatment Complications for Localized Prostate Cancer measure would add value to the PCHQR Program measure set, as discussed in detail below.

(2) Overview of Measure

The Surgical Treatment Complications for Localized Prostate Cancer measure addresses complications of a prostatectomy. The outcomes selected for this measure are urinary incontinence (UI) and erectile dysfunction (ED). Specifically, the measure uses claims to identify urinary incontinence and erectile dysfunction among patients undergoing localized prostate cancer surgery and uses this information to derive hospital-specific rates. A strong body of literature, including numerous recent systematic reviews, have demonstrated the burden of UI and ED for men following localized prostate surgery and ED.[598] [599] [600] [601] [602] By identifying facilities where adverse outcomes associated with prostatectomy are more common, this measure will help to highlight opportunities for quality improvement activities that will address and hopefully mitigate unwarranted variation in prostatectomy procedures.

The proposed measure would be calculated using information from Medicare fee-for-service (FFS) claims, resulting in no new data reporting for PCHs. We would publicly report the measure results to enable patients to make informed decisions about accessing localized prostate surgery and about the rates of potential complications. We will identify a specified timeframe for public reporting of this measure in future rulemaking. In addition, we note that there are currently no measures assessing complications of prostate surgery in the PCHQR Program measure set.

(3) Data Sources

We are proposing that we would calculate this measure on a yearly basis using Medicare administrative claims data. Specifically, we are proposing that the data collection period for each program year would span from July 1 of the year 2 years prior to the start of the program year to June 30 of the year 1 year prior to the start of the program year. Therefore, for the FY 2022 program year, we would begin calculating measure rates using PCH claims data from July 1, 2019 through June 30, 2020.

During the development of the measure, the measure steward convened a technical expert panel (TEP), comprising diverse clinical and quality measurement experts from the 11 PPS-exempt cancer hospitals, in 2016. We note that the TEP endorsed the ICHOM's recommendation to measure prostate-directed surgical treatment complication. Because the measure methodology assesses complications pre-surgery and post-surgery directed to the prostate, this necessitates the availability of claims data. In order to examine data collection burden and data reliability, the TEP requested an analysis of using Medicare claims to assess treatment complications in the ICHOM standard set. For this purpose, a SEER-Medicare dataset [603] was used to validate Medicare claims data. SEER datasets are commonly considered ''gold standard'' data for cancer stage and other clinical characteristics, and are often used to validate Medicare claims data, which are lacking in these details. The results of this analysis showed that the claims-based algorithm used by the

cancer treatment using the SEER-Medicare data. *Medical care.* 2002;40(8 Suppl):IV–62–68.

[591] Aizer AA, Gu X, Chen MH, et al. Cost implications and complications of overtreatment of low-risk prostate cancer in the United States. *Journal of the National Comprehensive Cancer Network.* 2015; 13(1):61–68.

[592] Hayes JH, Ollendorf DA, Pearson SD, et al. Active surveillance compared with initial treatment for men with low-risk prostate cancer: a decision analysis. *JAMA.* 2010; 304(21):2373–2380.

[593] Schmid M, Meyer CP, Reznor G, et al acial Differences in the Surgical Care of Medicare Beneficiaries With Localized Prostate Cancer. *JAMA oncology.* 2016; 2(1):85–93.

[594] Jiang R, Tomaszewski JJ, Ward KC, Uzzo RG, Canter DJ. The burden of overtreatment: comparison of toxicity between single and combined modality radiation therapy among low risk prostate cancer patients. *The Canadian journal of urology.* 2015; 22(1):7648–7655.

[595] Loeb S, Carter HB, Berndt SI, Ricker W, Schaeffer EM. Complications after prostate biopsy: data from SEER-Medicare. *The Journal of urology.* 2011; 186(5):1830–1834.

[596] Begg CB, Cramer LD, Hoskins WJ, Brennan MF. Impact of hospital volume on operative mortality for major cancer surgery. *JAMA.* 1998; 280(20):1747–1751.

[597] Localized Prostate Cancer Standard Set, available at: *http://www.ichom.org/medical-conditions/localized-prostate-cancer/.*

[598] Garcia-Baquero R, Fernandez-Avila CM, Alvarez-Ossorio JL. Functional results in the treatment of localized prostate cancer. An updated literature review. *Rev Int Androl.* 2018 Nov 22. pii: S1698–031X(18)30085–2.

[599] Du Y, Long Q, Guan B, Mu L, Tian J, Jiang Y, Bai X, Wu D. Robot-Assisted Radical Prostatectomy Is More Beneficial for Prostate Cancer Patients: A System Review and Meta-Analysis. *Med Sci Monit.* 2018 Jan 14;24:272–287.

[600] Wang X, Wu Y, Guo J, Chen H, Weng X, Liu X. Intrafascial nerve-sparing radical prostatectomy improves patients' postoperative continence recovery and erectile function: A pooled analysis based on available literatures. Medicine (Baltimore). 2018 Jul; 97(29):e11297.

[601] Wallis CJD, Glaser A, Hu JC, Huland H, Lawrentschuk N, Moon D, Murphy DG, Nguyen PL, Resnick MJ, Nam RK. Survival and Complications Following Surgery and Radiation for Localized Prostate Cancer: An International Collaborative Review. *Eur Urol.* 2018 Jan; 73(1):11–20.

[602] Huang X, Wang L, Zheng X, Wang X. Comparison of perioperative, functional, and oncologic outcomes between standard laparoscopic and robotic-assisted radical prostatectomy: a systemic review and meta-analysis. *Surg Endosc.* 2017 Mar; 31(3):1045–1060.

[603] SEER-Medicare Dataset. Available at: *https://healthcaredelivery.cancer.gov/seermedicare/overview/.*

measure could successfully identify patients with prostate cancer, thereby substantiating the use of Medicare claims as the data source for this measure.

(4) Measure Calculation

This outcome measure analyzes hospital/facility-level variation in patient-relevant outcomes during the year after prostate-directed surgery. Specifically, the measure uses claims to identify urinary incontinence and erectile dysfunction among patients undergoing localized prostate cancer surgery and uses this information to derive hospital-specific rates. Those outcomes are rescaled to a 0–100 scale, with 0=worst and 100=best. The numerator includes patients with diagnosis claims that could indicate adverse outcomes following prostate-directed surgery. The numerator is determined by: (1) Calculating the difference in the number of days with claims for incontinence or erectile dysfunction in the year after versus the year before prostate surgery for each patient; (2) truncating (by Winsorizing) to reduce the impact of outliers; (3) rescaling the difference from 0 (worst) to 100 (best); and (4) calculating the mean score for each hospital based on all of the difference values for all of the patients treated at that hospital. The denominator is determined by the following: Men age 66 or older at the time of prostate cancer diagnosis with at least two ICD diagnosis codes for prostate cancer separated by at least 30 days; men who survived at least one year after prostate directed therapy; codes for prostate cancer surgery (either open or minimally invasive/robotic prostatectomy) at any time after the first prostate cancer diagnosis; and continuous enrollment in Medicare Parts A and B (and no Medicare Part C (Medicare Advantage) enrollment)) from one year before through one year after prostate directed therapy. The measure code lists include all codes required for the numerator and denominator calculation.[604]

The proposed measure excludes patients with metastatic disease, patients with more than one nondermatologic malignancy, patients receiving chemotherapy, patients receiving radiation, and/or patients who die within 1 year after prostatectomy. We note that the validity of this measure would be threatened by inclusion of patients who did not meet the denominator criteria. Specifically, patients with more than one nondermatologic malignancy are excluded because a second cancer diagnosis during the measurement period could influence the outcomes. Further, patients receiving chemotherapy are excluded because guidelines for localized prostate cancers do not recommend chemotherapy for routine care; therefore, chemotherapy can indicate advanced disease or other unique clinical characteristics. Patients receiving radiation therapy are excluded because radiation therapy to the prostate can impact the occurrence of complications in these patients. Therefore, the impact of the surgery versus the radiation therapy in these patients cannot be determined. Lastly, patients who die within 1 year after prostatectomy are excluded because death is highly unlikely to be related to localized prostate cancer and unlikely to be related to the surgical complications. Thus, patients who die within the year following surgery likely die from an unrelated reason. As such, the measure will be calculated as the numerator divided by the denominator (in accordance with the denominator exclusions described above). Complete measure specifications for the proposed measure are available in the ''2018 Measures Under Consideration List'' Excel file, which can be accessed at: *http://www.qualityforum.org/map/.*

(5) Cohort

This measure includes adult male Medicare FFS beneficiaries, age 66 years and older, who have received prostate cancer directed surgery within the defined measurement period. We note that this measure cohort was determined in accordance with the defined measure denominator and its specified exclusions (discussed above) and based on testing conducted on the minimum number of patients attributed to the hospital associated with the claims for the procedure code for prostatectomy. The age of 66 at the time of prostate cancer diagnosis was chosen because per the denominator, a patient must have had Medicare claims data for 1 year prior to and 1 year after surgery. Additional methodology and measure development details are available in the ''2018 Measures Under Consideration List,'' which can be accessed at: *http://www.qualityforum.org/map/.*

(6) Risk Adjustment

The measure steward developed a mock risk-adjustment testing protocol based on the case-mix variables identified in the ICHOM data dictionary,[605] and TEP guidance. Specifically, the measure steward identified covariates that could be incorporated for potential risk-adjustment modeling. The covariates were not limited to those available in claims data; clinical covariates were also identified for analysis from SEER to determine adequacy of claims alone for valid measurement. Specifically, the following patient factors were controlled for when deriving the patient-level complication score: Age; year of surgery; other/unknown prostate cancer grade; and prostatectomy type. Hierarchical linear modeling was used to identify which patient, tumor, and hospital factors are associated with a higher IED score. After review of the results of the mock risk-adjustment testing efforts, it was determined that risk adjusting the measure did not yield results that demonstrate any statistically significant differences from the non-risk-adjusted results. The measure steward analyzed the correlation between the unadjusted performance scores and risk-adjusted performance scores, and observed that the correlation coefficients were above 95 percent in both analyses. Consequently, the measure steward elected to finalize the development of the measure without the implementation of a risk-adjustment model.

(7) Measure Application Partnership (MAP) Assessment of the Proposed Measure

In compliance with section 1890A(a)(2) of the Act, the proposed measure was included on a publicly available document entitled ''2018 Measures under Consideration Spreadsheet,'' [606] a list of quality and efficiency measures under consideration for use in various Medicare programs, and was reviewed by the MAP Hospital Workgroup. The MAP noted the importance of patient-relevant outcomes for patients who have undergone surgical treatment for prostate care, but encouraged CMS to resubmit the measure once the measure developer has better streamlined the reliability and validity testing methodologies.[607]

[604] 2018–2019 Measure Applications Partnership Workgroup Final Recommendations Excel spreadsheet. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[605] International Consortium for Health Outcomes Measurement (ICHOM) in the Localized Prostate Cancer Standard Set. *https://www.ichom.org/medical-conditions/localized-prostate-cancer/.*

[606] Measures Application Partnership ''2018 measures Under Consideration Spreadsheet.'' Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=88813.*

[607] MAP 2019 Considerations for Implementing Measures, Final Report. Available at: *http://www.qualityforum.org/Publications/2019/02/*

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Specifically, the MAP discussed the differences between surgical procedures (for example, open, closed, minimally invasive, robotic, among others) and recommended that non-open procedures be grouped separately.[608] The MAP also suggested the measure be risk-adjusted because of the concern of different rates of complications related to how the surgery is performed.[609]

In response to the concern raised by the MAP regarding the grouping of surgical procedures, we note that the measure is intended to calculate one overall facility rate for accountability purposes. However, given the guidance from the MAP, the steward has notified CMS that each hospital's performance will be stratified by prostatectomy procedure type (open versus not open) to add meaning for consumers and for hospital quality improvement. In response to the MAP's question of risk-adjustment, we note that risk-adjustment is limited for cancer patients when using claims data (for example, cancer stage not captured in claims data). Despite this, we reiterate that the steward conducted a mock risk-adjustment testing protocol and observed that risk-adjusting the measure did not demonstrate any statistically significant differences. As such, the steward chose not to include the risk-adjustment methodology for the measure.

Currently, we are unaware of an alternative quality measure assessing this measurement topic that is appropriate for the PCHQR Program. This measure is not endorsed by the NQF, and in our environmental scan of the NQF measures portfolio, we have not been able to identify a feasible and practical endorsed measure that addresses surgical procedures for localized prostate cancer. We believe this measure meets the requirement under section 1866(k)(3)(B) of the Act, which provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. In addition, we note this measure aligns with recent initiatives to increase the number of outcome measures in quality reporting programs. Lastly, this measure also aligns with the ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' domain of our Meaningful Measures Initiative,[610] and would fill an existing gap area of patient-focused episode of care in the PCHQR Program.

(8) Proposed Adoption of the Surgical Treatment Complications for Localized Prostate Cancer Measure

We believe this measure would be a valuable addition to the PCHQR Program because it is a high impact (as prostate cancer is a prevalent disease) outcome measure and it addresses reduction in harm. This is a hospital/facility-level, claims-based measure that analyzes variation in the occurrence of incontinence and/or erectile dysfunction during the year after prostate-directed surgery, which is one of the standard treatments for localized prostate cancer. Further, this measure has the potential to improve patient outcomes and decrease costs associated with managing adverse events. By identifying facilities where adverse outcomes associated with prostatectomy are more common, this measure would help to highlight opportunities for quality improvement that address unwarranted variation. This will facilitate improved compliance with guidelines from the American Urology Association (AUA) and other professional societies that call for minimizing the potential for therapy-related adverse outcomes.[611]

Lastly, this measure could be utilized as a tool to foster quality improvement and optimize outcomes for patients with localized prostate cancer. For the reasons outlined above, we are proposing to adopt the Surgical Treatment Complications for Localized Prostate Cancer measure for the FY 2022 program year and subsequent years.

c. Summary of Previously Finalized and Proposed PCHQR Program Measures for the FY 2022 Program Year and Subsequent Years

The table below summarizes the PCHQR Program measure set for the FY 2022 program year if we finalized our proposal to remove the External Beam Radiotherapy (EBRT) for Bone Metastases measure and our proposal to adopt the proposed Surgical Treatment Complications for Localized Prostate Cancer measure.

FY 2022 PCHQR Program Measure Set if Proposals To Remove One Measure and Adopt One Measure are Finalized

Short name	NQF No.	Measure name
Safety and Healthcare-Associated Infection (HAI)		
CAUTI	0138	Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.
CLABSI	0139	Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure.
HCP	0431	National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel.
Colon and Abdominal Hysterectomy SSI.	0753	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery].
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure.
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.
Clinical Process/Oncology Care Measures		
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life.
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer Not Admitted to Hospice.

MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx.

[608] Ibid.

[609] Ibid.

[610] Overview of CMS ''Meaningful Measures'' Initiative. Available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html.*

[611] Prostate Cancer Clinical Guidelines. Available at: *http://www.auanet.org/guidelines/clinically-localized-prostate-cancer-new-(aua/astro/suo-guideline-2017.*

FY 2022 PCHQR Program Measure Set if Proposals To Remove One Measure and Adopt One Measure are Finalized—Continued

Short name	NQF No.	Measure name
N/A	0383	Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology.
Intermediate Clinical Outcome Measures		
EOL–ICU	0213	Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life.
EOL–3DH	0216	Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days.
Patient Engagement/Experience of Care		
HCAHPS	0166	Hospital Consumer Assessment of Healthcare Providers and Systems.
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.
N/A	3188	30-Day Unplanned Readmissions for Cancer Patients.
N/A*	N/A	Surgical Treatment Complications for Localized Prostate Cancer Measure.

* Measure proposed for adoption for the FY 2022 program year and subsequent years.

6. Possible New Quality Measure Topics for Future Years

a. Background

As discussed in section I.A.2. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), we have begun analyzing our quality reporting and quality payment programs' measures using the framework we developed for the Meaningful Measures Initiative. We have also discussed future quality measure topics and quality measure domain areas in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50280), the FY 2016 IPPS/LTCH PPS final rule (80 FR 4979), the FY 2017 IPPS/LTCH PPS final rule (81 FR 25211), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38421 through 38423), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41618 through 41621).

In this proposed rule, we are again seeking public comment on the topics we should consider for quality measurement in the PCHQR Program. We are particularly interested in public comments on measures that could balance the need to assess pain management against efforts to ensure that providers are not incentivized to overprescribe opioids to patients in the PCH setting. We also are seeking public comment on potential future measures that could assess alternative pain management methodologies for cancer patients.

b. Overview of Pain Management Issues and Request for Comments on Pain Management Measures and Measurement Concepts for the Cancer Patient Population

As discussed earlier, we are proposing to remove the current pain management questions from the version of the HCAHPS Survey implemented in the PCHQR Program beginning with October 1, 2019 discharges in order to avoid any potential unintended consequences related to the perception that providers may be incentivized to overprescribe opioids to cancer patients. The opioid epidemic is a national crisis, and we are interested in the feasibility of adopting quality measures that examine a PCH's utilization of pain management strategies other than opioid prescriptions when furnishing care to its patients. We recognize that unintended opioid overdose fatalities have reached epidemic proportions in the last 20 years and are a major public health concern in the United States.[612] As such, reducing the number of unintended opioid overdoses is a priority for HHS. Concurrent prescriptions of opioids or opioids and benzodiazepines put patients at greater risk of unintended opioid overdose due to increased risk of respiratory depression.[613] [614] In addition, an analysis of more than 1 million hospital admissions in the United States found that over 43 percent of all patients with nonsurgical admissions were exposed to multiple opioids during their hospitalization.[615] As such, we believe that it is imperative to not inadvertently support the over-prescription of opioids by promoting opioids as a primary pain management remedy for cancer patients. In conjunction with that, we also recognize the need to be responsive to the unique needs of the cancer patient cohort by continually examining the quality measurement landscape for quality measures that balance pain management with efforts to address the opioid epidemic.

We recognize the importance of including quality measures that adequately assess cancer patient pain and quality measures that assess a PCH's use of alternative pain management methodologies. We believe that these types of measures can assess critical components of cancer care. Studies examining the frequency and quality of cancer pain management show room for improvement in these areas—for example, a systematic review revealed that, despite a 25-percent decrease in under-treatment of cancer pain between 2007 and 2013, approximately one-third of patients living with cancer still have pain that is inadequately treated.[616] Further, postsurgical complications related to inadequate pain management negatively affect patient welfare and hospital performance because of extended lengths of stay and readmissions, both

[612] Rudd, R., Aleshire, N., Zibbell, J., et al. ''Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014.'' MMWR, Jan 2016. 64(50);1378–82. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.*

[613] Dowell, D., Haegerich, T., Chou, R. ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' MMWR Recomm Rep 2016;65. Available at: *http://www.cdc.gov/media/dpk/2016/dpk-opioid-prescription-guidelines.html.*

[614] Jena, A., et al. ''Opioid prescribing by multiple providers in Medicare: retrospective observational study of insurance claims.'' *BMJ.* 2014; 348:g1393 doi: 10.1136/bmj.g1393. Available at: *http://www.bmj.com/content/348/bmj.g1393.*

[615] Herzig, S., Rothberg, M., Cheung, M., et al. ''Opioid utilization and opioid-related adverse events in nonsurgical patients in U.S. hospitals.'' Nov 2013. DOI: 10.1002/jhm.2102. Available at: *http://onlinelibrary.wiley.com/doi/10.1002/jhm.2102/abstract.*

[616] Optimal Pain Management for Patients with Cancer in the Modern Era. Available at: *https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21453.*

of which increase the cost of care.[617] This raises concern in the context of the patient safety issues related to pain management (that is, a patient's physical safety during the administration of sedatives and complications associated with catheter administration).[618] In addition, patients who have not been treated adequately for pain management may be reluctant to seek medical care for other health problems.[619]

On August 7, 2018, the Alliance of Dedicated Cancer Centers,[620] which is a consortium of cancer hospitals that includes among its members 10 of the 11 participating PCHs for the PCHQR Program, convened a group of expert stakeholders to discuss and provide recommendations regarding best practices for the future of pain measurement among cancer patients, within the context of the opioid crisis in the United States. Participants included cancer patient advocates, clinicians, researchers, and health care quality professionals. The participants discussed the pros and cons of various methods to collect and report performance measures related to cancer pain and cancer pain management. The participants acknowledged the importance of addressing the national opioid crisis. However, for cancer patients specifically, the participants unanimously supported ongoing pain-related quality measurement. Further, the participants indicated that the relatively high prevalence of pain symptoms in the cancer patient population,[621] particularly in patients with advanced disease or metastatic cancer, underscores the need for feasible, valid, and reliable pain measures. They also added that pain assessment offers clinicians the greatest utility when the information collected can be used to identify personalized pain management goals for patients.

Further, we are aware of the existence of other cancer-specific, non-survey, patient experience assessment tools that evaluate cancer patient pain and may be more appropriate than the HCAHPS Survey pain questions which we are proposing to remove in this proposed rule. As such, we believe there should be consideration given to the use of pain-related patient experience items for cancer patients, with a shifting focus toward Patient-Reported Outcome (PRO)-Performance Measures (PRO–PMs) in the mid and longer term (for example, 3 years, 5 years). Specifically, a growing body of research demonstrates the benefits of integration of PROs into oncology practice, including improved patient outcomes and survival.[622] [623]

Accordingly, we are seeking public comment on measures and measurement concepts that can be further developed that would assess appropriate pain management in the cancer patient population. Specific topics could include measures that assess cancer patient safety, patient and family education, and patient experience and engagement (specifically PRO–PMs) in the context of cancer pain management. We are inviting public comment on the potential future adoption of measures that assess post-treatment addiction prevention for cancer patients. Lastly, we are inviting public comment on existing measures or measurement concepts that evaluate pain management for cancer patients, and do not involve opioid use.

7. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for the PCHQR Program measures, and we periodically update those specifications. The specifications may be found on the QualityNet website at: *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863.*

We also use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program (79 FR 50281).

8. Public Display Requirements

a. Background

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review the data that are to be made public with respect to the PCH prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS website.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191 through 57192), we finalized that although we would continue to use rulemaking to establish what year we first publicly report data on each measure, we would publish the data as soon as feasible during that year. We also stated that our intent is to make the data available on at least a yearly basis, and that the time period for PCHs to review their data before the data are made public would be approximately 30 days in length. We announce the exact data review and public reporting timeframes on a CMS website and/or on our applicable Listservs.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41623) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 59149 through 59153), we finalized our public display requirements for the FY 2021 program year.

We recognize the importance of being transparent with stakeholders and keeping them abreast of any changes that arise with the PCHQR Program measure set. As such, we are making two proposals in this proposed rule regarding the timetable for the public display of data for specific PCHQR Program measures.

b. Proposed Public Display of the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure Beginning With CY 2020

We are proposing to begin public reporting of the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure in CY 2020. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57187), we stated that we would publicly report the risk-standardized admission rate (RSAR) and risk-standardized ED visit rate (RSEDR) for the Admissions and Emergency Department (ED) Visits for the Patients Receiving Outpatient Chemotherapy measure for all participating PCHs with 25 or more eligible patients per measurement period. We stated that this threshold allowed us to maintain a reliability of at least 0.4 for publicly reported data (as measured by the interclass correlation coefficient (ICC). We also noted that if a PCH did not meet the 25-eligible patient threshold, we would include a footnote on the *Hospital Compare* website indicating that the number of cases is too small to reliably measure that PCH's rate, but

[617] Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK2658/.*

[618] Ibid.

[619] Ibid.

[620] Alliance of Dedicate Cancer Centers website: *http://www.adcc.org/.*

[621] National Quality Forum. Patient Reported Outcomes (PROs) in Performance Measurement. Available at: *http://www.qualityforum.org/Publications/2012/12/Patient-Reported_Outcomes_in_Performance_Measurement.aspx.* Published December 2012.

[622] Basch E, Deal AM, Dueck AC, et al. Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment. *JAMA.* 2017; 318(2):197–198. doi:10.1001/jama.2017.7156.

[623] Denis, F et al. Patient-Reported Outcomes, Mobile Technology, and Response Burden. 2018 ASCO Annual Meeting. Abstract No: 6500.

that these patients and PCHs would still be included when calculating the national rates for both the RSAR and RSEDR (81 FR 57187). To prepare PCHs for the public reporting of this measure, we also indicated that we would conduct a confidential national reporting (dry run) of measure results. The objectives of the confidential national reporting were to: (1) Educate PCHs and other stakeholders about the measure; (2) allow PCHs to review their measure results and data prior to public reporting; (3) answer questions from PCHs and other stakeholders; (4) test the production and reporting process; and (5) identify potential technical changes to the measure specifications that might be needed.

We recently completed the confidential national reporting for this measure and have assessed the preliminary results to ensure data accuracy and completeness. Further, we confidentially reported results for the measure to the participating PCHs in October 2018, based on Medicare claims data that were collected on chemotherapy treatments performed from July 1, 2016–June 30, 2017. To execute this confidential reporting, we utilized facility-specific reports (FSRs), which allow facilities to preview measure results and patient data prior to public reporting. The FSRs included the following elements: Measure performance results; national results; detailed patient-level data used to calculate measure results; and a summary of each facility's patient-mix. To ensure continuity in the observed measure performance results, we intend to complete a subsequent round of confidential national reporting in the spring of 2019, using Medicare claims data from July 1, 2017 through June 30, 2018.

Given the success of our first round of confidential reporting and the associated timeline of our subsequent round of confidential reporting, we are proposing to begin publicly reporting performance data on the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure in CY 2020. We believe that this proposed timeline allows for more accurate assessment of measure results and allows both CMS and the participating PCHs adequate time to review all the confidential reporting results.

c. Public Display of Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Measures

(1) Proposed Public Display of the Colon and Abdominal Hysterectomy SSI, MRSA, CDI and HCP Measures in CY 2019

At present, all PCHs are reporting the CDC NHSN Healthcare-Associated Infection (HAI) Colon and Abdominal Hysterectomy SSI, MRSA, CDI, and HCP data to the National Healthcare Safety Network (NHSN) for purposes of the PCHQR Program. We finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41622) that we would provide stakeholders with performance data for these measures as soon as practicable (that is, we will publicly report it on the *Hospital Compare* website via the next available *Hospital Compare* release). In addition, we noted that the CDC announced that HAI data reported to the NHSN for 2015 will be used as the new baseline, serving as a new ''reference point'' for comparing progress.[624] Currently, these rebaselining efforts—specifically, generation and implementation of new predictive models used to calculate SIRs—are complete. As such, we are proposing to publicly report data for the Colon and Abdominal Hysterectomy SSI, MRSA, CDI, and HCP measures beginning with the October 2019 *Hospital Compare* release.

(2) Continued Deferral of Public Display of the CAUTI and CLABSI Measures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59149 through 59153), we finalized that we would not remove the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and the Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139) from the PCHQR measure set. We also noted that we will continue to defer public reporting for the CAUTI and CLABSI measures (83 FR 59153).

We are continuing to work alongside the CDC to evaluate the performance data for the updated, risk-adjusted versions of the CAUTI and CLABSI measures so that we can draw conclusions about their statistical significance in accordance with current risk adjustment methods defined by CDC. In order to allow adequate time for data collection by the CDC, submission of those data to CMS, and our review of the data for accuracy and completeness, we believe that the earliest we will be able to publicly display information on the revised versions of the CAUTI and CLABSI measures will be CY 2022. Therefore, we will continue to defer public reporting of the CAUTI and CLABSI measures and intend to provide stakeholders with performance data on the measures as soon as practicable.

d. Summary of Previously Finalized and Proposed Public Display Requirements for the PCHQR Program

Our previously finalized and proposed public display requirements for the PCHQR Program are shown in the following table:

PREVIOUSLY FINALIZED AND PROPOSED PUBLIC DISPLAY REQUIREMENTS FOR THE PCHQR PROGRAM

[Summary of previously adopted and newly proposed public display requirements]

Measures	Public reporting
• HCAHPS (NQF #0166) *	2016 and subsequent years.
• Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383)	
• External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822) **	2017 and subsequent years.
• American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753).	October of CY 2019.
• National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (NQF #1716).	
• National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).	
• National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).	

[624] Centers for Disease Control and Prevention. ''Paving Path Forward: 2015 Rebase line.'' Available at: *https://www.cdc.gov/nhsn/2015rebaseline/index.html.*

PREVIOUSLY FINALIZED AND PROPOSED PUBLIC DISPLAY REQUIREMENTS FOR THE PCHQR PROGRAM—Continued

[Summary of previously adopted and newly proposed public display requirements]

Measures	Public reporting
• Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	CY 2020.
• CAUTI (NQF #0138)	Deferred until CY 2022.
• CLABSI (NQF #0139)	

* In section VIII.B.2.b. of the preamble of this this proposed rule, we are proposing that beginning with October 2018 discharges, publicly reported data will not include responses Pain Management questions.

** In section VIII.B.4. of the preamble of this this proposed rule, we are proposing to remove this measure, beginning with the FY 2022 program year.

9. Form, Manner, and Timing of Data Submission

a. Background

Data submission requirements and deadlines for the PCHQR Program are posted on the QualityNet website at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772864228.*

b. Proposed Confidential National Reporting for Certain Existing PCHQR Measures

We are proposing to conduct a confidential national reporting for data collection of the following measures in the PCHQR measure set:

- Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life (NQF #0210);
- Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life (NQF #0213);
- Proportion of patients who died from cancer not admitted to hospice (NQF #0215);
- Proportion of patients who died from cancer admitted to hospice for less than 3 days (NQF #0216); and
- 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188).

(1) Background

We initially adopted the four end-of-life care measures in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38414 through 38420) for inclusion in the PCHQR Program beginning with the FY 2020 program year. We also finalized that the initial data collection period would be from July 1, 2017 through June 30, 2018 (82 FR 38424). After we adopted the measures, the American Society of Clinical Oncology (ASCO), which is the measure steward, updated their technical specifications. We believe that these updates are not substantive and that we do not need to use the rulemaking process to incorporate them. We also note that there has been no change in the measures' data source. Specifically, the measures will continue to be calculated using Medicare claims data.

We initially adopted the 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188) in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41614 through 41616). This is also a claims-based measure; adopted for implementation beginning with the FY 2021 program year and with an initial data collection period of October 1, 2018 through September 30, 2019 (83 FR 41616).

(2) Proposed Confidential National Reporting for Data Collection

To prepare PCHs for public reporting, we are proposing to conduct two confidential reporting periods of measure results prior to public reporting. Consistent with previous confidential national reporting efforts for measures in the PCHQR Program, the objectives of the confidential national reporting are to: (1) Educate PCHs and other stakeholders about the measures; (2) allow PCHs to review their measure results and data prior to public reporting; (3) answer questions from PCHs and other stakeholders; (4) test the production and reporting process; and (5) identify potential additional technical changes to the measure specifications that might be needed. We believe these confidential national reporting activities will enable hospitals to gain data collection and reporting experience familiarity with these refined measures for their efforts to improve quality and better understand the measure specifications and associated data. Confidential national reporting is important because it affords CMS an opportunity to examine a measure's performance prior to publicly sharing data with stakeholders and is a method of ensuring that the publicly reported measure performance results are as accurate as possible. Confidential national reporting will also allow both CMS and participating PCHs adequate time to review all the performance results for the respective measures. This will mitigate the possibility of CMS having to suppress inaccurate and/or inadequate measure data, because we will have had an opportunity to preview it over a broader span of time than the standard 30-day preview period associated with public reporting.

For the group end-of-life care measures, we are proposing to conduct confidential national reporting using Medicare claims data collected from July 1, 2019 through June 30, 2020. For the 30-Day Unplanned Readmissions for Cancer Patients measure, we are proposing to conduct confidential national reporting using Medicare claims data collected from October 1, 2019 through September 30, 2020. We plan to include measure results from the confidential national reporting in the facility-specific feedback reports (FSRs) that we provide to PCHs. The FSRs will include the following elements: Measure performance results, national results (based on the performance of the 11 PCHs), detailed patient-level data used to calculate measure results and a summary of each PCH's patient-mix.

10. Extraordinary Circumstances Exceptions (ECE) Policy Under the PCHQR Program

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41623 through 41624), for a discussion of the Extraordinary Circumstances Exceptions (ECE) policy under the PCHQR Program. In this proposed rule, we are not proposing any changes to this policy.

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as long-term care hospitals (LTCHs). Under the LTCH QRP, the Secretary must reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not complied with the LTCH QRP requirements specified for that fiscal year. For more information on the requirements we

have adopted for the LTCH QRP, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51744), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50853), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49725), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57193), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38425 through 38426), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634).

2. General Considerations Used for the Selection of Measures for the LTCH QRP

For a detailed discussion of the considerations we historically used for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728).

3. Quality Measures Currently Adopted for the FY 2021 LTCH QRP

The LTCH QRP currently has 15 measures for the FY 2021 LTCH QRP, which are set out in the following table:

QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2021 LTCH QRP

Short name	Measure name and data source
LTCH CARE Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Functional Assessment	Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support (NQF #2632).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay.
Ventilator Liberation	Ventilator Liberation Rate.
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).
CLABSI	National Healthcare Safety Network (NHSN) Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).
Claims-Based	
MSPB LTCH	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).
DTC	Discharge to Community—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).

4. LTCH QRP Quality Measure Proposals Beginning With the FY 2022 LTCH QRP

In this proposed rule, we are proposing to adopt two process measures for the LTCH QRP that would satisfy section 1899B(c)(1)(E)(ii) of the Act, which requires that the quality measures specified by the Secretary include measures with respect to the quality measure domain titled ''Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual when the individual transitions from a post-acute care (PAC) provider to another applicable setting, including a different PAC provider, a hospital, a critical access hospital, or the home of the individual.'' Given the length of this domain title, hereafter, we will refer to this quality measure domain as ''Transfer of Health Information.''

The two measures we are proposing to adopt are: (1) Transfer of Health Information to the Provider–Post-Acute Care (PAC); and (2) Transfer of Health Information to the Patient–Post-Acute Care (PAC). Both of these proposed measures support our Meaningful Measures priority of promoting effective communication and coordination of care, specifically the Meaningful Measure area of the transfer of health information and interoperability.

In addition to the two measure proposals, we are proposing to update the specifications for the Discharge to Community—Post Acute Care (PAC) LTCH QRP measure to exclude baseline nursing facility (NF) residents from the measure.

a. Proposed Transfer of Health Information to the Provider—Post-Acute Care (PAC) Measure

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure is a process-based measure that assesses whether or not a current reconciled medication list is given to the subsequent provider when a patient is discharged or transferred from his or her current PAC setting.

(1) Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency, and 9 percent who were discharged to SNFs.[625] The proportion of patients being discharged from an acute care hospital to a PAC setting was greater among beneficiaries enrolled in Medicare fee-for-service (FFS). Among Medicare FFS patients discharged from an acute hospital, 42 percent went directly to PAC settings. Of that 42 percent, 20 percent were discharged to a SNF, 18 percent were discharged to a home health agency (HHA), 3 percent were discharged to an IRF, and 1 percent were discharged to an LTCH.[626] Of the Medicare FFS beneficiaries with an LTCH stay in FYs 2016 and 2017, an estimated 9 percent were discharged or transferred to an acute care hospital, 18 percent discharged home with home health services, 38 percent discharged or transferred to a SNF, and 10 percent discharged or transferred to another PAC setting (for example, an IRF, a hospice, or another LTCH).[627]

The transfer and/or exchange of health information from one provider to another can be done verbally (for example, clinician-to-clinician communication in-person or by telephone), paper-based (for example, faxed or printed copies of records), and via electronic communication (for example, through a health information exchange (HIE) network using an electronic health/medical record (EHR/EMR), and/or secure messaging). Health information, such as medication information, that is incomplete or missing increases the likelihood of a patient or resident safety risk, and is often life-threatening.[628] [629] [630] [631] [632] [633] Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits, and medication errors.[634] [635] [636] [637] [638] [639] [640] [641] [642] [643] Communication has been cited as the third most frequent root cause in sentinel events, which The Joint Commission defines [644] as a patient safety event that results in death, permanent harm, or severe temporary harm. Failed or ineffective patient handoffs are estimated to play a role in 20 percent of serious preventable adverse events.[645] When care transitions are enhanced through care coordination activities, such as expedited patient information flow, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.[646] [647] [648] [649] [650]

Care transitions across health care settings have been characterized as complex, costly, and potentially hazardous, and may increase the risk for multiple adverse outcomes.[651] [652] The rising incidence of preventable adverse events, complications, and hospital readmissions have drawn attention to the importance of the timely transfer of health information and care preferences at the time of transition. Failures of care coordination, including poor communication of information, were estimated to cost the U.S. health care system between $25 billion and $45

[625] Tian, W. ''An all-payer view of hospital discharge to post-acute care,'' May 2016. Available at: *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp.*

[626] Ibid.

[627] RTI International analysis of Medicare claims data for index stays in LTCH 2016/2017. (RTI program reference: MM150).

[628] Kwan, J.L., Lo, L., Sampson, M., & Shojania, K.G., ''Medication reconciliation during transitions of care as a patient safety strategy: a systematic review,'' *Annals of Internal Medicine,* 2013, Vol. 158(5), pp. 397–403.

[629] Boockvar, K.S., Blum, S., Kugler, A., Livote, E., Mergenhagen, K.A., Nebeker, J.R., & Yeh, J., ''Effect of admission medication reconciliation on adverse drug events from admission medication changes,'' *Archives of Internal Medicine,* 2011, Vol. 171(9), pp. 860–861.

[630] Bell, C.M., Brener, S.S., Gunraj, N., Huo, C., Bierman, A.S., Scales, D.C., & Urbach, D.R., ''Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases,'' *JAMA,* 2011, Vol. 306(8), pp. 840–847.

[631] Basey, A.J., Krska, J., Kennedy, T.D., & Mackridge, A.J., ''Prescribing errors on admission to hospital and their potential impact: a mixed-methods study,'' *BMJ Quality & Safety,* 2014, Vol. 23(1), pp. 17–25.

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[633] Boling, P.A., ''Care transitions and home health care,'' *Clinical Geriatric Medicine,* 2009, Vol. 25(1), pp. 135–48.

[634] Barnsteiner, J.H., ''Medication Reconciliation: Transfer of medication information across settings—keeping it free from error,'' *The American Journal of Nursing,* 2005, Vol. 105(3), pp. 31–36.

[635] Arbaje, A.I., Kansagara, D.L., Salanitro, A.H., Englander, H.L., Kripalani, S., Jencks, S.F., & Lindquist, L.A., ''Regardless of age: incorporating principles from geriatric medicine to improve care transitions for patients with complex needs,'' *Journal of General Internal Medicine,* 2014, Vol. 29(6), pp. 932–939.

[636] Jencks, S.F., Williams, M.V., & Coleman, E.A., ''Rehospitalizations among patients in the Medicare fee-for-service program,'' *New England Journal of Medicine,* 2009, Vol. 360(14), pp. 1418–1428.

[637] Institute of Medicine. ''Preventing medication errors: quality chasm series,'' Washington, DC: The National Academies Press 2007. Available at: *https://www.nap.edu/read/11623/chapter/1.*

[638] Kitson, N.A., Price, M., Lau, F.Y., & Showler, G., ''Developing a medication communication framework across continuums of care using the Circle of Care Modeling approach,'' *BMC Health Services Research,* 2013, Vol. 13(1), pp. 1–10.

[639] Mor, V., Intrator, O., Feng, Z., & Grabowski, D.C., ''The revolving door of rehospitalization from skilled nursing facilities,'' *Health Affairs,* 2010, Vol. 29(1), pp. 57–64.

[640] Institute of Medicine. ''Preventing medication errors: quality chasm series,'' Washington, DC: The National Academies Press 2007. Available at: *https://www.nap.edu/read/11623/chapter/1.*

[641] Kitson, N.A., Price, M., Lau, F.Y., & Showler, G., ''Developing a medication communication framework across continuums of care using the Circle of Care Modeling approach,'' *BMC Health Services Research,* 2013, Vol. 13(1), pp. 1–10.

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[643] King, B.J., Gilmore-Bykovskyi, A.L., Roiland, R.A., Polnaszek, B.E., Bowers, B.J., & Kind, A.J. ''The consequences of poor communication during transitions from hospital to skilled nursing facility: a qualitative study,'' *Journal of the American Geriatrics Society,* 2013, Vol. 61(7), 1095–1102.

[644] The Joint Commission, ''Sentinel Event Policy'' available at: *https://www.jointcommission.org/sentinel_event_policy_and_procedures/.*

[645] The Joint Commission. ''Sentinel Event Data Root Causes by Event Type 2004–2015.'' 2016. Available at: *https://www.jointcommission.org/assets/1/23/jconline_Mar_2_2016.pdf.*

[646] Mor, V., Intrator, O., Feng, Z., & Grabowski, D.C., ''The revolving door of rehospitalization from skilled nursing facilities,'' *Health Affairs,* 2010, Vol. 29(1), pp. 57–64.

[647] Institute of Medicine, ''Preventing medication errors: quality chasm series,'' Washington, DC: The National Academies Press, 2007. Available at: *https://www.nap.edu/read/11623/chapter/1.*

[648] Starmer, A.J., Sectish, T.C., Simon, D.W., Keohane, C., McSweeney, M.E., Chung, E.Y., Yoon, C.S., Lipsitz, S.R., Wassner, A.J., Harper, M.B., & Landrigan, C.P., ''Rates of medical errors and preventable adverse events among hospitalized children following implementation of a resident handoff bundle,'' *JAMA,* 2013, Vol. 310(21), pp. 2262–2270.

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[650] Balaban R.B., Weissman J.S., Samuel P.A., & Woolhandler, S., ''Redefining and redesigning hospital discharge to enhance patient care: a randomized controlled study,'' *J Gen Intern Med,* 2008, Vol. 23(8), pp. 1228–33.

[651] Arbaje, A.I., Kansagara, D.L., Salanitro, A.H., Englander, H.L., Kripalani, S., Jencks, S.F., & Lindquist, L.A., ''Regardless of age: incorporating principles from geriatric medicine to improve care transitions for patients with complex needs,'' *Journal of General Internal Medicine,* 2014, Vol. 29(6), pp. 932–939.

[652] Simmons, S., Schnelle, J., Slagle, J., Sathe, N.A., Stevenson, D., Carlo, M., & McPheeters, M.L., ''Resident safety practices in nursing home settings.'' Technical Brief No. 24 (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290–2015–00003–I.) AHRQ Publication No. 16–EHC022–EF. Rockville, MD: Agency for Healthcare Research and Quality. May 2016. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK384624/.*

billion in wasteful spending in 2011.[653] The communication of health information and patient care preferences is critical to ensuring safe and effective transitions from one health care setting to another.[654] [655]

Patients in PAC settings often have complicated medication regimens and require efficient and effective communication and coordination of care between settings, including detailed transfer of medication information.[656] [657] [658] Individuals in PAC settings may be vulnerable to adverse health outcomes due to insufficient medication information on the part of their health care providers, and the higher likelihood for multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[659] [660] Preventable adverse drug events (ADEs) may occur after hospital discharge in a variety of settings including PAC.[661] A 2014 Office of Inspector General report found that 21 percent of Medicare patients in LTCHs experienced adverse events, with 31 percent of those events being medication related. Over half of the adverse events and temporary harm events were clearly or likely preventable.[662] Patient stays in LTCHs present more opportunities for harm events than other settings because the stays are longer. Medication errors and one-fifth of ADEs occur during transitions between settings, including admission to or discharge from a hospital to home or a PAC setting, or transfer between hospitals.[663] [664]

Patients in PAC settings are often taking multiple medications. Consequently, PAC providers regularly are in the position of starting complex new medication regimens with little knowledge of the patients or their medication history upon admission. Furthermore, inter-facility communication barriers delay resolving medication discrepancies during transitions of care.[665] Medication discrepancies are common,[666] and found to occur in 86 percent of all transitions, increasing the likelihood of ADEs.[667] [668] [669] Up to 90 percent of patients experience at least one medication discrepancy in the transition from hospital to home care, and discrepancies occur within all therapeutic classes of medications.[670] [671]

Transfer of a medication list between providers is necessary for medication reconciliation interventions, which have been shown to be a cost-effective way to avoid ADEs by reducing errors,[672] [673] [674] especially when medications are reviewed by a pharmacist using electronic medical records.[675]

(2) Stakeholder and Technical Expert Panel (TEP) Input

The proposed measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS Measures Management System Blueprint.

Our measure development contractors constituted a TEP which met on September 27, 2016,[676] January 27,

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[658] Brody, A.A., Gibson, B., Tresner-Kirsch, D., Kramer, H., Thraen, I., Coarr, M.E., & Rupper, R., ''High prevalence of medication discrepancies between home health referrals and Centers for Medicare and Medicaid Services home health certification and plan of care and their potential to affect safety of vulnerable elderly adults,'' Journal of the American Geriatrics Society, 2016, Vol. 64(11), pp. e166–e170.

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[662] Health and Human Services Office of Inspector General. Adverse Events in Long-Term-Care Hospitals: National Incidence Among Medicare Beneficiaries. (OEI–06–14–00530). 2018. Available at: *https://oig.hhs.gov/oei/reports/oei-06-14-00530.asp.*

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[672] Boockvar, K.S., Blum, S., Kugler, A., Livote, E., Mergenhagen, K.A., Nebeker, J.R., & Yeh, J., ''Effect of admission medication reconciliation on adverse drug events from admission medication changes,'' *Archives of Internal Medicine,* 2011, Vol. 171(9), pp. 860–861.

[673] Kwan, J.L., Lo, L., Sampson, M., & Shojania, K.G., ''Medication reconciliation during transitions of care as a patient safety strategy: a systematic review,'' *Annals of Internal Medicine,* 2013, Vol. 158(5), pp. 397–403.

[674] Chhabra, P.T., Rattinger, G.B., Dutcher, S.K., Hare, M.E., Parsons, K., L., & Zuckerman, I.H., ''Medication reconciliation during the transition to and from long-term care settings: a systematic review,'' *Res Social Adm Pharm,* 2012, Vol. 8(1), pp. 60–75.

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[676] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at: *https://www.cms.gov/*

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2017, and August 3, 2017 [677] to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened this TEP on April 20, 2018 for the purpose of obtaining expert input on the proposed measure, including the measure's reliability, components of face validity, and feasibility of being implemented across PAC settings. Overall, the TEP was supportive of the proposed measure, affirming that the measure provides an opportunity to improve the transfer of medication information. A summary of the April 20, 2018 TEP proceedings titled ''Transfer of Health Information TEP Meeting 4—June 2018'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. The comments received expressed overall support for the measure. Several commenters suggested ways to improve the measure, primarily related to what types of information should be included at transfer. We incorporated this input into development of the proposed measure. The summary report for the March 19 to May 3, 2018 public comment period titled ''IMPACT—Medication Profile Transferred Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

(3) Pilot Testing

The proposed measure was tested between June and August 2018 in a pilot test that involved 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 records. Analysis of agreement between coders within each participating facility (266 qualifying pairs) indicated a 93-percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented across PAC settings. Further, more than half of the sites that participated in the pilot test stated during the debriefing interviews that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report titled ''Transfer of Health Information 2018 Pilot Test Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

(4) Measure Applications Partnership (MAP) Review and Related Measures

We included the proposed measure in the LTCH QRP section of the 2018 Measures Under Consideration (MUC) list. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure can promote the transfer of important medication information. The MAP also suggested that CMS consider a measure that can be adapted to capture bi-directional information exchange, and recommended that the medication information transferred include important information about supplements and opioids. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_PAC-LTC.aspx.*

As part of the measure development and selection process, we also identified one NQF-endorsed quality measure similar to the proposed measure, titled Documentation of Current Medications in the Medical Record (NQF #0419, CMS eCQM ID: CMS68v8). This measure was adopted as one of the recommended adult core clinical quality measures for eligible professionals for the EHR Incentive Program beginning in 2014 and was also adopted under the Merit-based Incentive Payment System (MIPS) quality performance category beginning in 2017. The measure is calculated based on the percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all resources immediately available on the date of the encounter.

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) measure addresses the transfer of information whereas the NQF-endorsed measure #0419 assesses the documentation of medications, but not the transfer of such information. This is important as the proposed measure assesses for the transfer of medication information for the proposed measure calculation. Further, the proposed measure utilizes standardized patient assessment data elements (SPADEs), which is a requirement for measures specified under the Transfer of Health Information measure domain under section 1899B(c)(1)(E) of the Act, whereas NQF #0419 does not.

After review of the NQF-endorsed measure, we determined that the proposed Transfer of Health Information to the Provider—Post-Acute Care (PAC) measure better addresses the Transfer of Health Information measure domain, which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through the post-acute care assessment instruments. Section 1886(m)(5)(D)(i) of the Act requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the National Quality Form (NQF). However, when a feasible and practical measure has not been NQF endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1886(m)(5)(D)(ii) of the Act allows the Secretary to specify a measure that is not NQF endorsed as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For the reasons discussed above, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1886(m)(5)(D)(ii) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP_Summary_Report_Final-June-2017.pdf.

[677] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meetings-2-3-Summary-Report_Final_Feb2018.pdf.*

(5) Quality Measure Calculation

The proposed Transfer of Health Information to the Provider—Post-Acute Care (PAC) quality measure is calculated as the proportion of patient stays with a discharge assessment indicating that a current reconciled medication list was provided to the subsequent provider at the time of discharge. The proposed measure denominator is the total number of LTCH patient stays, regardless of payer, ending in discharge to a ''subsequent provider,'' which is defined as a short-term general acute-care hospital, intermediate care (intellectual and developmental disabilities providers), home under care of an organized home health service organization or hospice, hospice in an institutional facility, a SNF, another LTCH, an IRF, an inpatient psychiatric facility, or a CAH. These health care providers were selected for inclusion in the denominator because they are identified as subsequent providers on the discharge destination item that is currently included on the LTCH Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set or LCDS). The proposed measure numerator is the number of LTCH patient stays with an LCDS discharge assessment indicating a current reconciled medication list was provided to the subsequent provider at the time of discharge. For additional technical information about this proposed measure, we refer readers to the document titled, ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* The data source for the proposed quality measure is the LCDS assessment instrument for LTCH patients.

For more information about the data submission requirements we are proposing for this measure, we refer readers to section VIII.C.8.d. of the preamble of this proposed rule.

b. Proposed Transfer of Health Information to the Patient—Post-Acute Care (PAC) Measure

Beginning with the FY 2022 LTCH QRP, we are proposing to adopt the Transfer of Health Information to the Patient—Post-Acute Care (PAC) measure, a measure that satisfies the IMPACT Act domain of Transfer of Health Information, with data collection for discharges beginning October 1, 2020. This process-based measure assesses whether or not a current reconciled medication list was provided to the patient, family, or caregiver when the patient was discharged from a PAC setting to a private home/apartment, a board and care home, assisted living, a group home, transitional living or home under care of an organized home health service organization, or a hospice.

(1) Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency.[678] Of the Medicare FFS beneficiaries with an LTCH stay in fiscal years 2016 and 2017, an estimated 18 percent were discharged home with home health services, nine percent were discharged home with self-care, and two percent were discharged with home hospice services.[679]

The communication of health information, such as a reconciled medication list, is critical to ensuring safe and effective patient transitions from health care settings to home and/or other community settings. Incomplete or missing health information, such as medication information, increases the likelihood of a patient safety risk, often life-threatening.[680] [681] [682] [683] [684] Individuals who use PAC care services are particularly vulnerable to adverse health outcomes due to their higher likelihood of having multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[685] [686] Upon discharge to home, individuals in PAC settings may be faced with numerous medication changes, new medication regimes, and follow-up details.[687] [688] [689] The efficient and effective communication and coordination of medication information may be critical to prevent potentially deadly adverse effects. When care coordination activities enhance care transitions, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.[690] [691]

Finally, the transfer of a patient's discharge medication information to the patient, family, or caregiver is common practice and supported by discharge planning requirements for participation in Medicare and Medicaid programs.[692] [693] Most PAC EHR systems

[678] Tian, W. ''An all-payer view of hospital discharge to postacute care,'' May 2016. Available at: *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp.*

[679] RTI International analysis of Medicare claims data for index stays in LTCH 2016/2017. (RTI program reference: MM150).

[680] Kwan, J.L., Lo, L., Sampson, M., & Shojania, K.G. ''Medication reconciliation during transitions of care as a patient safety strategy: A systematic review,'' Annals of Internal Medicine, 2013, Vol. 158(5), pp. 397–403.

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[682] Bell, C.M., Brener, S.S., Gunraj, N., Huo, C., Bierman, A.S., Scales, D.C., & Urbach, D.R. ''Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases,'' *JAMA,* 2011, Vol. 306(8), pp. 840–847.

[683] Basey, A.J., Krska, J., Kennedy, T.D., & Mackridge, A.J. ''Prescribing errors on admission to hospital and their potential impact: A mixed-methods study,'' *BMJ Quality & Safety,* 2014, Vol. 23(1), pp. 17–25.

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[685] Brody, A.A., Gibson, B., Tresner-Kirsch, D., Kramer, H., Thraen, I., Coarr, M.E., & Rupper, R. ''High prevalence of medication discrepancies between home health referrals and Centers for Medicare and Medicaid Services home health certification and plan of care and their potential to affect safety of vulnerable elderly adults,'' *Journal of the American Geriatrics Society,* 2016, Vol. 64(11), pp. e166–e170.

[686] Chhabra, P.T., Rattinger, G.B., Dutcher, S.K. Hare, M.E., Parsons, K.L., & Zuckerman, I.H. ''Medication reconciliation during the transition to and from long-term care settings: A systematic review,'' *Res Social Adm Pharm,* 2012, Vol. 8(1), pp. 60–75.

[687] Brody, A.A., Gibson, B., Tresner-Kirsch, D., Kramer, H., Thraen, I., Coarr, M.E., & Rupper, R. ''High prevalence of medication discrepancies between home health referrals and Centers for Medicare and Medicaid Services home health certification and plan of care and their potential to affect safety of vulnerable elderly adults,'' *Journal of the American Geriatrics Society,* 2016, Vol. 64(11), pp. e166–e170.

[688] Bell, C.M., Brener, S.S., Gunraj, N., Huo, C., Bierman, A.S., Scales, D.C., & Urbach, D.R. ''Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases,'' *JAMA,* 2011, Vol. 306(8), pp. 840–847.

[689] Sheehan, O.C., Kharrazi, H., Carl, K.J., Leff, B., Wolff, J.L., Roth, D.L., Gabbard, J., & Boyd, C.M. ''Helping older adults improve their medication experience (HOME) by addressing medication regimen complexity in home healthcare,'' *Home Healthcare Now.* 2018, Vol. 36(1), pp. 10–19.

[690] Mor, V., Intrator, O., Feng, Z., & Grabowski, D.C. ''The revolving door of rehospitalization from skilled nursing facilities,'' *Health Affairs,* 2010, Vol. 29(1), pp. 57–64.

[691] Starmer, A.J., Sectish, T.C., Simon, D.W., Keohane, C., McSweeney, M.E., Chung, E.Y., Yoon, C.S., Lipsitz, S.R., Wassner, A.J., Harper, M.B., & Landrigan, C.P. ''Rates of medical errors and preventable adverse events among hospitalized children following implementation of a resident handoff bundle,'' *JAMA,* 2013, Vol. 310(21), pp. 2262–2270.

[692] CMS, ''Revision to state operations manual (SOM), Hospital Appendix A—Interpretive Guidelines for 42 CFR 482.43, Discharge Planning'' May 17, 2013. Available at: *https://www.cms.gov/*

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generate a discharge medication list to promote patient participation in medication management, which has been shown to be potentially useful for improving patient outcomes and transitional care.[694]

(2) Stakeholder and TEP Input

The proposed measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS Measures Management System Blueprint.

Our measure development contractors constituted a TEP which met on September 27, 2016,[695] January 27, 2017, and August 3, 2017 [696] to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened this TEP on April 20, 2018 to seek expert input on the measure. Overall, the TEP members supported the proposed measure, affirming that the measure provides an opportunity to improve the transfer of medication information. Most of the TEP members believed that the measure could improve the transfer of medication information to patients, families, and caregivers. Several TEP members emphasized the importance of transferring information to patients and their caregivers in a clear manner using plain language. A summary of the April 20, 2018 TEP proceedings titled ''Transfer of Health Information TEP Meeting 4—June 2018'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. Several commenters noted the importance of ensuring that the instruction provided to patients and caregivers is clear and understandable to promote transparent access to medical record information and meet the goals of the IMPACT Act. The summary report for the March 19 to May 3, 2018 public comment period titled ''IMPACT—Medication Profile Transferred Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

(3) Pilot Testing

Between June and August 2018, we held a pilot test involving 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 assessments. Analysis of agreement between coders within each participating facility (241 qualifying pairs) indicated an 87-percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented across PAC settings. Further, more than half of the sites that participated in the pilot test stated, during debriefing interviews, that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report titled ''Transfer of Health Information 2018 Pilot Test Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

(4) Measure Applications Partnership (MAP) Review and Related Measures

We included the proposed measure in the LTCH QRP section of the 2018 MUC list. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure can promote the transfer of important medication information to the patient. The MAP recommended that providers transmit medication information to patients that is easy to understand because health literacy can impact a person's ability to take medication as directed. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_PAC-LTC.aspx.*

Section 1886(m)(5)(D)(i) of the Act, requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the NQF. However, when a feasible and practical measure has not been NQF endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1886(m)(5)(D)(ii) of the Act allows the Secretary to specify a measure that is not NQF endorsed as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Therefore, in the absence of any NQF-endorsed measures that address the proposed Transfer of Health Information to the Patient—Post-Acute Care (PAC), which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through the post-acute care assessment instruments, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1886(m)(5)(D)(ii) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

(5) Quality Measure Calculation

The calculation of the proposed Transfer of Health Information to the Patient—Post-Acute Care (PAC) measure would be based on the proportion of patient stays with a discharge assessment indicating that a current

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Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-32.pdf.

693 The State Operations Manual Guidance to Surveyors for Long Term Care Facilities (Guidance § 483.21(c)(1) Rev. 11–22–17) for discharge planning process. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.*

694 Toles, M., Colon-Emeric, C., Naylor, M.D., Asafu-Adjei, J., Hanson, L.C. ''Connect-home: Transitional care of skilled nursing facility patients and their caregivers,'' *Am Geriatr Soc.,* 2017, Vol. 65(10), pp. 2322–2328.

695 Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP_Summary_Report_Final-June-2017.pdf.*

696 Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meetings-2-3-Summary-Report_Final_Feb2018.pdf.*

reconciled medication list was provided to the patient, family, or caregiver at the time of discharge.

The proposed measure denominator is the total number of LTCH patient stays, regardless of payer, ending in discharge to a private home/apartment, a board and care home, assisted living, a group home, transitional living or home under care of an organized home health service organization, or a hospice. These locations were selected for inclusion in the denominator because they are identified as home locations on the discharge destination item that is currently included on the LCDS. The proposed measure numerator is the number of LTCH patient stays with an LCDS discharge assessment indicating a current reconciled medication list was provided to the patient, family, or caregiver at the time of discharge. For technical information about this proposed measure, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* Data for the proposed quality measure would be calculated using data from the LCDS assessment instrument for LTCH patients.

For more information about the data submission requirements we are proposing for this measure, we refer readers to section VIII.C.8.d. of the preamble of this proposed rule.

c. Proposed Update to the Discharge to Community—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) Measure

We are proposing to update the specifications for the Discharge to Community—PAC LTCH QRP measure to exclude baseline nursing facility (NF) residents from the measure. This measure reports an LTCH's risk-standardized rate of Medicare FFS patients who are discharged to the community following an LTCH stay, do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. We adopted this measure in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57207 through 57215).

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57211), we addressed public comments recommending exclusion of LTCH patients who were baseline NF residents, as these patients lived in a NF prior to their LTCH stay and may not be expected to return to the community following their LTCH stay. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38449), we addressed public comments expressing support for a potential future modification of the measure that would exclude baseline NF residents; commenters stated that the exclusion would result in the measure more accurately portraying quality of care provided by LTCHs, while controlling for factors outside of LTCH control.

We assessed the impact of excluding baseline NF residents from the measure using CY 2015 and CY 2016 data and found that this exclusion impacted both patient- and facility-level discharge to community rates. We defined baseline NF residents as LTCH patients who had a long-term NF stay in the 180 days preceding their hospitalization and LTCH stay, with no intervening community discharge between the NF stay and qualifying hospitalization for measure inclusion. Baseline NF residents represented 9.2 percent of the measure population after all measure exclusions were applied. Observed patient-level discharge to community rates were significantly lower for baseline NF residents (1.44 percent) compared with non-NF residents (23.89 percent). The national observed patient-level discharge to community rate was 21.82 percent when baseline NF residents were included in the measure, increasing to 23.89 percent when they were excluded from the measure. After excluding baseline NF residents, 39.2 percent of LTCHs had an increase in their risk-standardized discharge to community rate that exceeded the increase in the national observed patient-level discharge to community rate.

Based on public comments received and our impact analysis, we are proposing to exclude baseline NF residents from the Discharge to Community—PAC LTCH QRP measure beginning with the FY 2020 LTCH QRP, with baseline NF residents defined as LTCH patients who had a long-term NF stay in the 180 days preceding their hospitalization and LTCH stay, with no intervening community discharge between the NF stay and hospitalization.

For additional technical information regarding the Discharge to Community—PAC LTCH QRP measure, including technical information about the proposed exclusion, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

5. LTCH QRP Quality Measures, Measure Concepts, and Standardized Patient Assessment Data Elements Under Consideration for Future Years: Request for Information

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the measures, standardized patient assessment data elements (SPADEs), and concepts under consideration listed in the table below for future years in the LTCH QRP.

FUTURE MEASURES, MEASURE CONCEPTS, AND STANDARDIZED PATIENT ASSESSMENT DATA ELEMENTS (SPADES) UNDER CONSIDERATION FOR THE LTCH QRP

Quality Measures and Measure Concepts
Functional mobility outcomes.
Sepsis.
Opioid use and frequency.
Exchange of electronic health information and interoperability.
Nutritional status.
Standardized Patient Assessment Data Elements (SPADEs)
Cognitive complexity, such as executive function and memory.
Dementia.
Bladder and bowel continence including appliance use and episodes of incontinence.

FUTURE MEASURES, MEASURE CONCEPTS, AND STANDARDIZED PATIENT ASSESSMENT DATA ELEMENTS (SPADES) UNDER CONSIDERATION FOR THE LTCH QRP—Continued

Care preferences, advance care directives, and goals of care.
Caregiver Status.
Veteran Status.
Health disparities and risk factors, including education, sex and gender identity, and sexual orientation.

While we will not be responding to specific comments submitted in response to this Request for Information in the FY 2020 IPPS/LTCH PPS final rule, we intend to use this input to inform our future measure and SPADE development efforts.

6. Proposed Standardized Patient Assessment Data Reporting Beginning With the FY 2022 LTCH QRP

Section 1886(m)(5)(F)(ii) of the Act requires that, for fiscal year 2019 and each subsequent year, LTCHs must report standardized patient assessment data (SPADE), required under section 1899B(b)(1) of the Act. Section 1899B(a)(1)(C) of the Act requires, in part, the Secretary to modify the PAC assessment instruments in order for PAC providers, including LTCHs, to submit SPADEs under the Medicare program. Section 1899B(b)(1)(A) of the Act requires PAC providers to submit SPADEs under applicable reporting provisions (which, for LTCHs, is the LTCH QRP) with respect to the admissions and discharges of an individual (and more frequently as the Secretary deems appropriate), and section 1899B(b)(1)(B) of the Act defines standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) of the Act and that is with respect to the following categories: (1) Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an impaired ability to hear, see, or swallow; and (6) other categories deemed necessary and appropriate by the Secretary.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20100 through 20116), we proposed to adopt SPADEs that would satisfy the first five categories. In the FY 2018 IPPS/LTCH PPS final rule, commenters expressed support for our adoption of SPADEs in general, including support for our broader standardization goal and support for the clinical usefulness of specific proposed SPADEs. However, we did not finalize the majority of our SPADE proposals in recognition of the concern raised by many commenters that we were moving too fast to adopt the SPADEs and modify our assessment instruments in light of all of the other requirements we were also adopting under the IMPACT Act at that time (82 FR 38457 through 38458). In addition, we noted our intention to conduct extensive testing to ensure that the standardized patient assessment data elements we select are reliable, valid, and appropriate for their intended use (82 FR 38451 through 38452).

We did, however, finalize the adoption of SPADEs for two of the categories described in section 1899B(b)(1)(B) of the Act: (1) Functional status: Data elements currently reported by LTCHs to calculate the measure Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and (2) Medical conditions and comorbidities: The data elements used to calculate the pressure ulcer measures, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and the replacement measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. We stated that these data elements were important for care planning, known to be valid and reliable, and already being reported by LTCHs for the calculation of quality measures (82 FR 38453 through 38454).

Since we issued the FY 2018 IPPS/LTCH PPS final rule, LTCHs have had an opportunity to familiarize themselves with other new reporting requirements that we have adopted under the IMPACT Act. We have also conducted further testing of the SPADEs, as described more fully below, and believe this testing supports the use of the SPADEs in our PAC assessment instruments. Therefore, we are now proposing to adopt many of the same SPADEs that we previously proposed to adopt, along with other SPADEs.

We are proposing that LTCHs would be required to report these SPADEs beginning with the FY 2022 LTCH QRP. If finalized as proposed, LTCHs would be required to report these data with respect to LTCH admissions and discharges that occur between October 1, 2020 and December 31, 2020 for the FY 2022 LTCH QRP. Beginning with the FY 2023 LTCH QRP, we are proposing that LTCHs must report data with respect to admissions and discharges that occur during the subsequent calendar year (for example, CY 2021 for the FY 2023 LTCH QRP, CY 2022 for the FY 2024 LTCH QRP).

We are also proposing that LTCHs that submit the Hearing, Vision, Race, and Ethnicity SPADEs with respect to admission only will be deemed to have submitted those SPADEs with respect to both admission and discharge, because it is unlikely that the assessment of those SPADEs at admission will differ from the assessment of the same SPADEs at discharge.

In selecting the proposed SPADEs below, we considered the burden of assessment-based data collection and aimed to minimize additional burden by evaluating whether any data that is currently collected through one or more PAC assessment instruments could be collected as SPADE. In selecting the proposed SPADEs below, we also took into consideration the following factors with respect to each data element:

(1) Overall clinical relevance;

(2) Interoperable exchange to facilitate care coordination during transitions in care;

(3) Ability to capture medical complexity and risk factors that can inform both payment and quality; and

(4) Scientific reliability and validity, general consensus agreement for its usability.

In identifying the SPADEs proposed below, we also drew on input from several sources, including TEPs held by our data element contractor, public input, and the results of a recent National Beta Test of candidate data elements conducted by our data element contractor (hereafter ''National Beta Test'').

The National Beta Test collected data from 3,121 patients and residents across 143 LTCHs, SNFs, IRFs, and HHAs from November 2017 to August 2018 to

evaluate the feasibility, reliability, and validity of the candidate data elements across PAC settings. The National Beta Test also gathered feedback on the candidate data elements from staff who administered the test protocol in order to understand usability and workflow of the candidate data elements. More information on the methods, analysis plan, and results for the National Beta Test are available in the document titled, ''Development and Evaluation of Candidate Standardized Patient Assessment Data Elements: Findings from the National Beta Test (Volume 2),'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Further, to inform the proposed SPADEs, we took into account feedback from stakeholders, as well as from technical and clinical experts, including feedback on whether the candidate data elements would support the factors described above. Where relevant, we also took into account the results of the Post-Acute Care Payment Reform Demonstration (PAC PRD) that took place from 2006 to 2012.

7. Proposed Standardized Patient Assessment Data by Category

a. Functional Status Data

We are proposing to adopt six functional status data elements as SPADEs under the category of functional status under section 1899B(b)(1)(B)(i) of the Act. These six data elements are: Car transfer; Walking 10 feet on uneven surfaces; 1-step (curb); 4 steps; 12 steps; and Picking up object. We are proposing to add these to the LCDS as SPADEs under section 1899B(b)(1)(B)(i) of the Act. We adopted these six mobility data elements into the SNF, IRF, and HH QRPs as SPADEs under their respective patient/resident assessment instruments. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38429 through 38430), we finalized our definition of ''standardized patient assessment data'' as patient assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply. In order for these six mobility data elements to be in all four PAC assessment instruments, we are proposing that they also meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of such data under section 1886(m)(5)(F)(i) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1886(m)(5)(F)(ii) of the Act.

The data elements listed above were implemented in the IRF QRP and SNF QRP when we adopted the quality measures, Change in Mobility Score (NQF #2634) and Discharge Mobility Score (NQF #2636), into the IRF QRP in the FY 2016 IRF PPS final rule (80 FR 47111 through 47120) and the SNF QRP in the FY 2018 SNF PPS final rule (82 FR 36577 through 36593). In addition, we implemented these six mobility data elements in the HH setting. The CY 2018 HH PPS final rule (82 FR 51733 through 51734) finalized that these six mobility data elements meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act.

The six mobility data elements are currently collected in Section GG: Functional Abilities and Goals located in the current versions of the MDS, OASIS, and the IRF–PAI assessment instruments. For more information on the six functional mobility data elements, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We are proposing to adopt the functional mobility data elements as SPADEs for use in the LTCH QRP.

b. Cognitive Function and Mental Status Data

A number of underlying conditions, including dementia, stroke, traumatic brain injury, side effects of medication, metabolic and/or endocrine imbalances, delirium, and depression, can affect cognitive function and mental status in PAC patient and resident populations.[697] The assessment of cognitive function and mental status by PAC providers is important because of the high percentage of patients and residents with these conditions,[698] and because these assessments provide opportunity for improving quality of care.

Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,[699] [700] [701] and promising treatments for severe traumatic brain injury are currently being tested.[702] For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,[703] [704] [705] [706] and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.[707]

In alignment with our Meaningful Measures Initiative, accurate assessment of cognitive function and mental status of patients and residents in PAC is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. For example, standardized assessment of cognitive function and mental status of patients and residents in PAC will support establishing a baseline for identifying

[697] National Institute on Aging. (2014). Assessing Cognitive Impairment in Older Patients. A Quick Guide for Primary Care Physicians. Retrieved from: *https://www.nia.nih.gov/alzheimers/publication/assessing-cognitive-impairment-older-patients.*

[698] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 4 of 4). Research Triangle Park, NC: RTI International.

[699] Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics,* 35, 208–11.

[700] Graff M.J., Vernooij-Dassen M.J., Thijssen M., Dekker J., Hoefnagels W.H., Rikkert M.G.O. (2006). Community Based Occupational Therapy for Patients with Dementia and their Care Givers: Randomised Controlled Trial. BMJ, 333(7580): 1196.

[701] Bherer L., Erickson K.I., Liu-Ambrose T. (2013). A Review of the Effects of Physical Activity and Exercise on Cognitive and Brain Functions in Older Adults. Journal of Aging Research, 657508.

[702] Giacino J.T., Whyte J., Bagiella E., et al. (2012). Placebo-controlled trial of amantadine for severe traumatic brain injury. New England Journal of Medicine, 366(9), 819–826.

[703] Alexopoulos G.S., Katz I.R., Reynolds C.F. 3rd, Carpenter D., Docherty J.P., Ross R.W. (2001). Pharmacotherapy of depression in older patients: A summary of the expert consensus guidelines. *Journal of Psychiatric Practice,* 7(6), 361–376.

[704] Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. *Biological Psychiatry,* 52(3), 293–303.

[705] Hollon S.D., Jarrett R.B., Nierenberg A.A., Thase M.E., Trivedi M., Rush A.J. (2005). Psychotherapy and medication in the treatment of adult and geriatric depression: Which monotherapy or combined treatment? *Journal of Clinical Psychiatry,* 66(4), 455–468.

[706] Wagenaar D, Colenda CC, Kreft M, Sawade J, Gardiner J, Poverejan E. (2003). Treating depression in nursing homes: Practice guidelines in the real world. *J Am Osteopath Assoc.* 103(10), 465–469.

[707] Crespy SD, Van Haitsma K, Kleban M, Hann CJ. Reducing Depressive Symptoms in Nursing Home Residents: Evaluation of the Pennsylvania Depression Collaborative Quality Improvement Program. J Healthc Qual. 2016. Vol. 38, No. 6, pp. e76–e88.

changes in cognitive function and mental status (for example, delirium), anticipating the patient's or resident's ability to understand and participate in treatments during a PAC stay, ensuring patient and resident safety (for example, risk of falls), and identifying appropriate support needs at the time of discharge or transfer. SPADEs will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care through facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable SPADEs assessing cognitive function and mental status are needed in order to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events. We describe each of the proposed cognitive function and mental status data SPADEs below.

• Brief Interview for Mental Status (BIMS)

We are proposing that the data elements that comprise the BIMS meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20100 through 20101), dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life and increased health care costs and mortality.[708] This makes assessment of mental status and early detection of cognitive decline or impairment critical in the PAC setting. The intensity of routine nursing care is higher for patients and residents with cognitive impairment than those without, and dementia is a significant variable in predicting readmission after discharge to the community from PAC providers.[709]

The BIMS is a performance-based cognitive assessment screening tool that assesses repetition, recall with and without prompting, and temporal orientation. The data elements that make up the BIMS are seven questions on the repetition of three words, temporal orientation, and recall that result in a cognitive function score. The BIMS was developed to be a brief, objective screening tool, with a focus on learning and memory. As a brief screener, the BIMS was not designed to diagnose dementia or cognitive impairment, but rather to be a relatively quick and easy to score assessment that could identify cognitively impaired patients as well as those who may be at risk for cognitive decline and require further assessment. It is currently in use in two of the PAC assessments: The MDS used by SNFs and the IRF–PAI used by IRFs. For more information on the BIMS, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The data elements that comprise the BIMS were first proposed as SPADEs in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20100 through 20101). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for use of the BIMS, noting that it is reliable, feasible to use across settings, and will provide useful information about patients and residents. We also stated that those commenters had noted that the data collected through the BIMS will provide a clearer picture of patient or resident complexity, help with the care planning process, and be useful during care transitions and when coordinating across providers. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the BIMS, with several commenters noting the importance of routine assessment of cognitive status and supporting the use of the BIMS to identify individuals with cognitive impairment. However, commenters expressed concerns about not having recent, comprehensive field testing of the proposed data elements. In addition, some commenters were critical of the BIMS, citing burden of administering the items and its limitation in assessing mild cognitive impairment and ''functional'' cognition related to executive function and everyday decision-making.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the BIMS was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the BIMS to be feasible and reliable for use with PAC patients and residents. More information about the performance of the BIMS in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In, addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements, and the TEP supported the assessment of patient or resident cognitive status at both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Some commenters expressed concern that the BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including mild cognitive impairment. A summary of the

[708] Agüero-Torres, H., Fratiglioni, L., Guo, Z., Viitanen, M., von Strauss, E., & Winblad, B. (1998). ''Dementia is the major cause of functional dependence in the elderly: 3-year follow-up data from a population-based study.'' Am J of Public Health 88(10): 1452–1456.

[709] RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM. Research Triangle Park, NC. 2016.

public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We understand the concerns raised by stakeholders that BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including functional cognition and MCI, but note that the purpose of the BIMS data elements as SPADEs is to screen for cognitive impairment in a broad population. We also acknowledge that further cognitive tests may be required based on a patient's condition and will take this feedback into consideration in the development of future standardized assessment data elements. However, taking together the importance of assessing for cognitive status, stakeholder input, and strong test results, we are proposing that the BIMS data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act, and to adopt the BIMS as standardized patient assessment data for use in the LTCH QRP.

- Confusion Assessment Method (CAM)

We are proposing that the data elements that comprise the Confusion Assessment Method (CAM) meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20101 through 20102), the CAM was developed to identify the signs and symptoms of delirium. It results in a score that suggests whether a patient or resident should be assigned a diagnosis of delirium. Because patients and residents with multiple comorbidities receive services from PAC providers, it is important to assess delirium, which is associated with a high mortality rate and prolonged duration of stay in hospitalized older adults.[710] Assessing these signs and symptoms of delirium is clinically relevant for care planning by PAC providers.

The CAM is a patient assessment that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment. The CAM is currently in use in two of the PAC assessments: A four-item version of the CAM is used in the MDS in SNFs, and a six-item version of the CAM is used in the LCDS in LTCHs. We are proposing to replace the version of the CAM currently used in the LCDS with the four-item version of the CAM currently used in the MDS. The proposed four-item version assesses acute change in mental status, inattention, disorganized thinking, and altered level of consciousness. For more information on the CAM, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The data elements that comprise the CAM were first proposed as SPADEs in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20101 through 20102). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for use of the CAM, noting that it would provide important information for care planning and care coordination and, therefore, contribute to quality improvement. We also stated that those commenters noted it is particularly helpful in distinguishing delirium and reversible confusion from other types of cognitive impairment. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments (82 FR 20101 through 20102) in support of the CAM. Commenters supported the continued use of the CAM in the LCDS. However, commenters expressed concerns about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the CAM was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the CAM to be feasible and reliable for use with PAC patients and residents. More information about the performance of the CAM in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although they did not specifically discuss the CAM data elements, the TEP supported the assessment of patient or resident cognitive status with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/*

[710] Fick, D.M., Steis, M.R., Waller, J.L., & Inouye, S.K. (2013). ''Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults.'' *J of Hospital Med* 8(9): 500–505.

IMPACT-Act-Downloads-and-Videos.html.

Taking together the importance of assessing for delirium, stakeholder input, and strong test results, we are proposing that the CAM data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act, and to adopt the CAM as standardized patient assessment data for use in the LTCH QRP.

• Patient Health Questionnaire–2 to 9 (PHQ–2 to 9)

We are proposing that the Patient Health Questionnaire–2 to 9 (PHQ–2 to 9) data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements are based on the PHQ–2 mood interview, which focuses on only the two cardinal symptoms of depression, and the longer PHQ–9 mood interview, which assesses presence and frequency of nine signs and symptoms of depression. The name of the data element, the PHQ–2 to 9, refers to an embedded a skip pattern that transitions patients with a threshold level of symptoms in the PHQ–2 to the longer assessment of the PHQ–9. The skip pattern is described further below.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20102 through 20103), depression is a common and under-recognized mental health condition. Assessments of depression help PAC providers better understand the needs of their patients and residents by: Prompting further evaluation after establishing a diagnosis of depression; elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge.

The proposed PHQ–2 to 9 is based on the PHQ–9 mood interview. The PHQ–2 consists of questions about only the first two symptoms addressed in the PHQ–9: Depressed mood and anhedonia (inability to feel pleasure), which are the cardinal symptoms of depression. The PHQ–2 has performed well as both a screening tool for identifying depression, to assess depression severity, and to monitor patient mood over time.[711] [712] If a patient demonstrates signs of depressed mood and anhedonia under the PHQ–2, then the patient is administered the lengthier PHQ–9. This skip pattern (also referred to as a gateway) is designed to reduce the length of the interview assessment for patients who fail to report the cardinal symptoms of depression. The design of the PHQ–2 to 9 reduces the burden that would be associated with the full PHQ–9, while ensuring that patients with indications of depressive symptoms based on the PHQ–2 receive the longer assessment.

Components of the proposed data elements are currently used in the OASIS for HHAs (PHQ–2) and the MDS for SNFs (PHQ–9). For more information on the PHQ–2 to 9, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We proposed the PHQ–2 data elements as SPADEs in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20102 through 20103). In that proposed rule we stated that the proposal was informed by input we received from the TEP convened by our data element contractor on April 6 and 7, 2016. The TEP members particularly noted that the brevity of the PHQ–2 made it feasible to administer with low burden for both assessors and PAC patients or residents. A summary of the April 6 and 7, 2016 TEP meeting titled ''SPADE Technical Expert Panel Summary (First Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

That rule proposal was also informed by public input that we received through a call for input published on the CMS Measures Management System Blueprint website. Input was submitted from August 12 to September 12, 2016 on three versions of the PHQ depression screener: The PHQ–2; the PHQ–9; and the PHQ–2 to 9 with the skip pattern design. Many commenters were supportive of the standardized assessment of mood in PAC settings, given the role that depression plays in well-being. Several commenters expressed support for an approach that would use PHQ–2 as a gateway to the longer PHQ–9 while still potentially reducing burden on most patients and residents, as well as test administrators, and ensuring the administration of the PHQ–9, which exhibits higher specificity,[713] for patients and residents who showed signs and symptoms of depression on the PHQ–2. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal to use the PHQ–2 in the FY 2018 IPPS/LTCH PPS proposed rule, we received comments agreeing that it was important to standardize the assessment of depression in patients receiving PAC services. Many commenters also raised concerns about the ability of the PHQ–2 to correctly identify all patients with signs and symptoms of depression and noted that the proposed PHQ–2 was not supported by recent, comprehensive field testing. In response to these comments, we carried out additional testing, and we provide our findings below.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the PHQ–2 to 9 data elements were included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the PHQ–2 to 9 to be feasible and reliable for use with PAC patients and residents. More information about the performance of the PHQ–2 to 9 in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of

[711] Li, C., Friedman, B., Conwell, Y., & Fiscella, K. (2007). ''Validity of the Patient Health Questionnaire 2 (PHQ-2) in identifying major depression in older people.'' *J of the A Geriatrics Society,* 55(4): 596–602.

[712] Löwe, B., Kroenke, K., & Gräfe, K. (2005). ''Detecting and monitoring depression with a two-item questionnaire (PHQ–2).'' *J of Psychosomatic Research,* 58(2): 163–171.

[713] Arroll B, Goodyear-Smith F, Crengle S, Gunn J, Kerse N, Fishman T, et al. Validation of PHQ–2 and PHQ–9 to screen for major depression in the primary care population. *Annals of family medicine.* 2010;8(4):348–53. doi: 10.1370/afm.1139 pmid:20644190; PubMed Central PMCID: PMC2906530.

soliciting input on the PHQ–2 to 9. The TEP was supportive of the PHQ–2 to 9 data element set as a screener for signs and symptoms of depression. The TEP's discussion noted that symptoms evaluated by the full PHQ–9 (for example, concentration, sleep, appetite) had relevance to care planning and the overall well-being of the patient or resident, but that the gateway approach of the PHQ–2 to 9 would be appropriate as a depression screening assessment, as it depends on the well-validated PHQ–2 and focuses on the cardinal symptoms of depression. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for depression, stakeholder input, and strong test results, in this proposed rule, we are proposing that the PHQ–2 to 9 data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act, and to adopt the PHQ–2 to 9 as standardized patient assessment data for use in the LTCH QRP.

c. Special Services, Treatments, and Interventions Data

Special services, treatments, and interventions performed in PAC can have a major effect on an individual's health status, self-image, and quality of life. The assessment of these special services, treatments, and interventions in PAC is important to ensure the continuing appropriateness of care for the patients and residents receiving them, and to support care transitions from one PAC provider to another, an acute care hospital, or discharge. In alignment with our Meaningful Measures Initiative, accurate assessment of special services, treatments, and interventions of patients and residents served by PAC providers is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care.

For example, standardized assessment of special services, treatments, and interventions used in PAC can promote patient and resident safety through appropriate care planning (for example, mitigating risks such as infection or pulmonary embolism associated with central intravenous access), and identifying life-sustaining treatments that must be continued, such as mechanical ventilation, dialysis, suctioning, and chemotherapy, at the time of discharge or transfer. Standardized assessment of these data elements will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through, for example, facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing special services, treatments, and interventions are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

A TEP convened by our data element contractor provided input on the proposed data elements for special services, treatments, and interventions. In a meeting held on January 5 and 6, 2017, this TEP found that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice, and that the collection of these data by means of a list and checkbox format would conform with common workflow for PAC providers. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Comments on the category of special services, treatments, and interventions were also submitted by stakeholders during the FY 2018 IPPS/LTCH PPS proposed rule public comment period. Although a few commenters noted the burden that the data elements for special services, treatments, and interventions will place on assessors and providers, we also received support for these data elements, noting their ability to inform care planning and care coordination.

Information on data element performance in the National Beta Test, which collected data between November 2017 and August 2018, is reported within each data element proposal below. Clinical staff who participated in the National Beta Test supported these data elements because of their importance in conveying patient or resident significant health care needs, complexity, and progress. However, clinical staff also noted that, despite the simple ''check box'' format of these data element, they sometimes needed to consult multiple information sources to determine a patient's or resident's treatments.

- Cancer Treatment: Chemotherapy (IV, Oral, Other)

We are proposing that the Chemotherapy (IV, Oral, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20103 through 20104), chemotherapy is a type of cancer treatment that uses drugs to destroy cancer cells. It is sometimes used when a patient has a malignancy (cancer), which is a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy have serious side effects, including nausea/vomiting, extreme fatigue, risk of infection due to a suppressed immune system, anemia, and an increased risk of bleeding due to low platelet counts. Oral chemotherapy can be as potent as chemotherapy given by IV, and can be significantly more convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be

exercised in handling and transporting chemotherapy drugs. IV chemotherapy is administered either peripherally or more commonly given via an indwelling central line, which raises the risk of bloodstream infections. Given the significant burden of malignancy, the resource intensity of administering chemotherapy, and the side effects and potential complications of these highly-toxic medications, assessing the receipt of chemotherapy is important in the PAC setting for care planning and determining resource use. The need for chemotherapy predicts resource intensity, both because of the complexity of administering these potent, toxic drug combinations under specific protocols, and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) for IV chemotherapy require significant resources.

The Chemotherapy (IV, Oral, Other) data element consists of a principal data element (Chemotherapy) and three response option sub-elements: IV chemotherapy, which is generally resource-intensive; Oral chemotherapy, which is less invasive and generally requires less intensive administration protocols; and a third category, Other, provided to enable the capture of other less common chemotherapeutic approaches. This third category is potentially associated with higher risks and is more resource intensive due to chemotherapy delivery by other routes (for example, intraventricular or intrathecal). If the assessor indicates that the patient is receiving chemotherapy on the principal Chemotherapy data element, the assessor would then indicate by which route or routes (for example, IV, Oral, Other) the chemotherapy is administered.

A single Chemotherapy data element that does not include the proposed three sub-elements is currently in use in the MDS in SNFs. For more information on the Chemotherapy (IV, Oral, Other) data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Chemotherapy data element was proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20103 through 20104). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the IV Chemotherapy data element and suggested it be included as standardized patient assessment data. Commenters stated that assessing the use of chemotherapy services is relevant to share across the care continuum to facilitate care coordination and care transitions and noted the validity of the data element. Commenters also noted the importance of capturing all types of chemotherapy, regardless of route, and stated that collecting data only on patients and residents who received chemotherapy by IV would limit the usefulness of this standardized data element. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Chemotherapy data element other than concerns about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Chemotherapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Chemotherapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Chemotherapy data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions. Although the TEP members did not specifically discuss the Chemotherapy data elements, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for chemotherapy, stakeholder input, and strong test results, we are proposing that the Chemotherapy (IV, Oral, Other) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Chemotherapy (IV, Oral, Other) data element as standardized patient assessment data for use in the LTCH QRP.

- Cancer Treatment: Radiation

We are proposing that the Radiation data element meets the definition of

standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20104 through 20105), radiation is a type of cancer treatment that uses high-energy radioactivity to stop cancer by damaging cancer cell DNA, but it can also damage normal cells. Radiation is an important therapy for particular types of cancer, and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. Assessing whether a patient or resident is receiving radiation therapy is important to determine resource utilization because PAC patients and residents will need to be transported to and from radiation treatments, and monitored and treated for side effects after receiving this intervention. Therefore, assessing the receipt of radiation therapy, which would compete with other care processes given the time burden, would be important for care planning and care coordination by PAC providers.

The proposed data element consists of the single Radiation data element. The Radiation data element is currently in use in the MDS in SNFs. For more information on the Radiation data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Radiation data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20104 through 20105). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the Radiation data element, noting its importance and clinical usefulness for patients in PAC settings, due to the side effects and consequences of radiation treatment on patients that need to be considered in care planning and care transitions, the feasibility of the item, and the potential for it to improve quality. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Radiation data element other than concerns about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Radiation data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Radiation data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Radiation data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for radiation, stakeholder input, and strong test results, we are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Radiation data element as standardized patient assessment data for use in the LTCH QRP.

- Respiratory Treatment: Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System)

We are proposing that the Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20105), we proposed a similar set of data elements related to oxygen therapy. Oxygen therapy provides a patient or resident with extra oxygen when medical conditions such as chronic obstructive pulmonary disease, pneumonia, or severe asthma prevent the patient or resident from getting enough oxygen from breathing. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment such as a source of oxygen, delivery systems (for example, oxygen concentrator, liquid oxygen containers, and high-pressure systems), the patient interface (for example, nasal cannula or mask), and other accessories (for example, regulators, filters, tubing). The data element proposed here captures patient or resident use of three types of oxygen therapy (intermittent, continuous, and high-concentration oxygen delivery system), which reflects the intensity of care needed, including the level of monitoring and bedside care required. Assessing the receipt of this service is

important for care planning and resource use for PAC providers.

The proposed data element, Oxygen Therapy, consists of the principal Oxygen Therapy data element and three response option sub-elements: Continuous (whether the oxygen was delivered continuously, typically defined as >=14 hours per day); Intermittent; or High-concentration oxygen delivery system. Based on public comments and input from expert advisors about the importance and clinical usefulness of documenting the extent of oxygen use, we added a third sub-element, high-concentration oxygen delivery system, to the sub-elements, which previously included only intermittent and continuous. If the assessor indicates that the patient is receiving oxygen therapy on the principal oxygen therapy data element, the assessor then would indicate the type of oxygen the patient receives (for example, Continuous, Intermittent, High-concentration oxygen delivery system).

These three proposed sub-elements were developed based on similar data elements that assess oxygen therapy, currently in use in the MDS in SNFs (''Oxygen Therapy''), previously used in the OASIS–C2 (''Oxygen (intermittent or continuous)''), and a data element tested in the PAC PRD that focused on intensive oxygen therapy (''High O2 Concentration Delivery System with FiO2 >40 percent''). For more information on the proposed Oxygen Therapy (Continuous, Intermittent, High-concentration oxygen delivery system) data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Oxygen Therapy (Continuous, Intermittent) data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20105). In that proposed rule, we stated that the proposal was informed by input we received on the single data element, Oxygen (inclusive of intermittent and continuous oxygen use), through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed the importance of the Oxygen data element, noting feasibility of this item in PAC, and the relevance of it to facilitating care coordination and supporting care transitions, but suggesting that the extent of oxygen use be documented. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general, which are summarized above. In response to our proposal, we received comments in support of the Oxygen Therapy (Continuous, Intermittent) data element. A commenter also requested the addition of a third sub-element to differentiate between receipt of high-flow oxygen (6 or more liters per minute) and regular oxygen, noting that it is a form of respiratory support commonly used on patients with acute respiratory failure and, therefore, could be used as an indicator of patient severity in future analysis. We also received public comments related to concerns about not having recent, comprehensive field testing of proposed data elements. In response to public comments, we added a third sub-element to the Oxygen Therapy data element and carried out additional testing, which we provide our findings below.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Oxygen Therapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Oxygen Therapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Oxygen Therapy data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for oxygen therapy, stakeholder input, and strong test results, we are proposing that the Oxygen Therapy (Intermittent, Continuous, High-concentration oxygen delivery system) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Oxygen Therapy (Intermittent, Continuous, High-concentration oxygen delivery system) data element as standardized patient assessment data for use in the LTCH QRP.

- Respiratory Treatment: Suctioning (Scheduled, As Needed)

We are proposing that the Suctioning (Scheduled, As needed) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and

interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20105 through 20106), suctioning is a process used to clear secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients' care plans, both to prevent the accumulation of secretions than can lead to aspiration pneumonias (a common condition in patients with inadequate gag reflexes), and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which often lead to desaturations and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions, or can be done as needed when secretions become so prominent that gurgling or choking is noted, or a sudden desaturation occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource intensive if it occurs every hour, for example, rather than once a shift. It also signifies an underlying medical condition that prevents the patient from clearing his/her secretions effectively (such as after a stroke, or during an acute respiratory infection). Generally, suctioning is necessary to ensure that the airway is clear of secretions which can inhibit successful oxygenation of the individual. The intent of suctioning is to maintain a patent airway, the loss of which can lead to death, or complications associated with hypoxia.

The Suctioning (Scheduled, As needed) data element consists of a principal data element, and two sub-elements: Scheduled; and As needed. These sub-elements capture two types of suctioning. Scheduled indicates suctioning based on a specific frequency, such as every hour. As needed means suctioning only when indicated. If the assessor indicates that the patient is receiving suctioning on the principal Suctioning data element, the assessor would then indicate the frequency (for example, Scheduled, As needed). The proposed data element is based on an item currently in use in the MDS in SNFs which does not include our proposed two sub-elements, as well as data elements tested in the PAC PRD that focused on the frequency of suctioning required for patients with tracheostomies (''Trach Tube with Suctioning: Specify most intensive frequency of suctioning during stay [Every __h hours]''). For more information on the Suctioning data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Suctioning data elements were first proposed as SPADEs in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20105 through 20106). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12, to September 12, 2016 expressed support of the Suctioning data element currently used in the MDS in SNFs. The input noted the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. We also received public comments suggesting that we examine the frequency of suctioning in order to better understand the use of staff time, the impact on a patient or resident's capacity to speak and swallow, and intensity of care required. Based on these comments, we decided to add two sub-elements (Scheduled and As needed) to the suctioning element. The proposed Suctioning data element includes both the principal Suctioning data element that is included on the MDS in SNFs and two sub-elements, Scheduled and As needed. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Suctioning data element other than concerns about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Suctioning data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Suctioning data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Suctioning data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicited additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-*

Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

Taking together the importance of assessing for suctioning, stakeholder input, and strong test results, we are proposing that the Suctioning (Scheduled, As needed) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Suctioning (Scheduled, As needed) data element as standardized patient assessment data for use in the LTCH QRP.

• Respiratory Treatment: Tracheostomy Care

We are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20106 through 20107), a tracheostomy provides an air passage to help a patient or resident breathe when the usual route for breathing is obstructed or impaired. Generally, in all of these cases, suctioning is necessary to ensure that the tracheostomy is clear of secretions, which can inhibit successful oxygenation of the individual. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, albeit permanent or temporary, warrants careful monitoring and immediate intervention if the tracheostomy becomes occluded or if the device used becomes dislodged. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the ostomy is performed by the patient) in general the presence of such as device is associated with increased patient risk, and clinical care services will necessarily include close monitoring to ensure that no life-threatening events occur as a result of the tracheostomy. In addition, tracheostomy care, which primarily consists of cleansing, dressing changes, and replacement of the tracheostomy cannula (tube), is a critical part of the care plan. Regular cleansing is important to prevent infection such as pneumonia and to prevent any occlusions with which there are risks for inadequate oxygenation.

The proposed data element consists of the single Tracheostomy Care data element. The proposed data element is currently in use in the MDS in SNFs (''Tracheostomy care''). For more information on the Tracheostomy Care data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Tracheostomy Care data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20106 through 20107). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support of the Tracheostomy Care data element, noting the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

During the FY 2018 IPPS/LTCH PPS proposed rule comment period, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Tracheostomy Care data element other than concerns about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Tracheostomy Care data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Tracheostomy Care data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Tracheostomy Care data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for tracheostomy care, stakeholder input, and strong test results, we are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Tracheostomy Care data element as standardized patient assessment data for use in the LTCH QRP.

• Respiratory Treatment: Non-Invasive Mechanical Ventilator (BiPAP, CPAP)

We are proposing that the Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP], Continuous Positive Airway Pressure [CPAP]) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20107), BiPAP and CPAP are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air via electronic cycling throughout the breathing cycle (BiPAP) or through a mask continuously (CPAP). Assessment of non-invasive mechanical ventilation is important in care planning, as both CPAP and BiPAP are resource-intensive (although less so than invasive mechanical ventilation) and signify underlying medical conditions about the patient or resident who requires the use of this intervention. Particularly when used in settings of acute illness or progressive respiratory decline, additional staff (for example, respiratory therapists) are required to monitor and adjust the CPAP and BiPAP settings and the patient or resident may require more nursing resources.

The proposed data element, Non-invasive Mechanical Ventilator (BIPAP, CPAP), consists of the principal Non-invasive Mechanical Ventilator data element and two sub-elements: BiPAP and CPAP. If the assessor indicates that the patient is receiving non-invasive mechanical ventilation on the principal Non-invasive Mechanical Ventilator data element, the assessor would then indicate which type (that is, BIPAP, CPAP). Data elements that assess non-invasive mechanical ventilation are currently included on LCDS for the LTCH setting (''Non-invasive Ventilator (BIPAP, CPAP)''), and the MDS for the SNF setting (''Non-invasive Mechanical Ventilator (BiPAP/CPAP)''). We are proposing to expand the existing ''Non-invasive Ventilator (BiPAP, CPAP)'' data element on the LCDS, by retaining and renaming the main data element to be Non-invasive Mechanical Ventilator and adding two sub-elements for BiPAP and CPAP. For more information on the Non-invasive Mechanical Ventilator (BIPAP, CPAP) data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Non-invasive Mechanical Ventilator data element was first proposed as SPADEs in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20107). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website on a single data element, BiPAP/CPAP, that captures equivalent clinical information but uses a different label, to what is currently in use on the MDS in SNFs and LCDS in LTCHs. Input submitted from August 12 to September 12, 2016 expressed support of the data element, noting the feasibility in PAC, and the relevance to facilitating care coordination and supporting care transitions. In addition, there was support in the public comment responses for separating out BiPAP and CPAP as distinct sub-elements, as they are therapies used for different types of patients and residents. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Non-invasive Mechanical Ventilator data element other than concerns about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Non-invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Non-invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Non-invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for non-invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element, with a principal data element and two sub-elements, meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element as standardized patient

assessment data for use in the LTCH QRP.

• Respiratory Treatment: Invasive Mechanical Ventilator

We are proposing that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20107 through 20108), invasive mechanical ventilation includes ventilators and respirators that ventilate the patient through a tube that extends via the oral airway into the pulmonary region or through a surgical opening directly into the trachea. Thus, assessment of invasive mechanical ventilation is important in care planning and risk mitigation. Ventilation in this manner is a resource-intensive therapy associated with life-threatening conditions without which the patient or resident would not survive. However, ventilator use has inherent risks requiring close monitoring. Failure to adequately care for the patient or resident who is ventilator dependent can lead to iatrogenic events such as death, pneumonia and sepsis. Mechanical ventilation further signifies the complexity of the patient's underlying medical or surgical condition. Of note, invasive mechanical ventilation is associated with high daily and aggregate costs.[714]

The proposed data element, Invasive Mechanical Ventilator, consists of a single data element. Data elements that capture invasive mechanical ventilation are currently in use in the MDS in SNFs and LCDS in LTCHs. We are proposing that this data element will be collected at admission from the ''Invasive Mechanical Ventilation Support upon Admission to the LTCH'' data element that is already included on the LCDS, and through a new, added data element at discharge. For more information on the Invasive Mechanical Ventilator data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Invasive Mechanical Ventilator data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20107 through 20108). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website on data elements that assess invasive ventilator use and weaning status that were tested in the PAC PRD (''Ventilator—Weaning'' and ''Ventilator—Non-Weaning''). Input submitted from August 12 to September 12, 2016 expressed support for this data element, highlighting the importance of this information in supporting care coordination and care transitions. Some commenters expressed concern about the appropriateness for standardization, given the prevalence of ventilator weaning across PAC providers; the timing of administration; how weaning is defined; and how weaning status relates to quality of care. These public comments guided our decision to propose a single data element focused on current use of invasive mechanical ventilation only, which does not attempt to capture weaning status. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the Special Services, Treatments, and Interventions data elements in general, and support from one commenter on the Invasive Mechanical Ventilator data element. However, concerns were expressed about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Invasive Mechanical Ventilator data element that assesses the use of an invasive mechanical ventilator meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Invasive Mechanical Ventilator data element as

[714] Wunsch, H., Linde-Zwirble, W. T., Angus, D.C., Hartman, M.E., Milbrandt, E. B., & Kahn, J.M. (2010). ''The epidemiology of mechanical ventilation use in the United States.'' *Critical Care Med* 38(10): 1947–1953.

standardized patient assessment data for use in the LTCH QRP.

• Intravenous (IV) Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other)

We are proposing that the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

We proposed a similar set of data elements related to IV medications in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20108 through 20109). IV medications are solutions of a specific medication (for example, antibiotics, anticoagulants) administered directly into the venous circulation via a syringe or intravenous catheter (tube). IV medications are administered via intravenous push, single, intermittent, or continuous infusion through a tube placed into the vein. Further, IV medications are more resource intensive to administer than oral medications, and signify a higher patient complexity (and often higher severity of illness).

The clinical indications for each of the sub-elements of the IV Medications data element (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) are very different. IV antibiotics are used for severe infections when: The bioavailability of the oral form of the medication would be inadequate to kill the pathogen; an oral form of the medication does not exist; or the patient is unable to take the medication by mouth. IV anticoagulants refer to anti-clotting medications (that is, ''blood thinners''). IV anticoagulants are commonly used for hospitalized patients who have deep venous thrombosis, pulmonary embolism, or myocardial infarction, as well as those undergoing interventional cardiac procedures. Vasoactive medications refer to the IV administration of vasoactive drugs, including vasopressors, vasodilators, and continuous medication for pulmonary edema, which increase or decrease blood pressure or heart rate. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess each separately in PAC. Knowing whether or not patients are receiving IV medication and the type of medication provided by each PAC provider will improve quality of care.

The IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) data element we are proposing consists of a principal data element (IV Medications) and four response option sub-elements: Antibiotics; Anticoagulants; Vasoactive Medications; and Other. The Vasoactive Medications sub-element was not proposed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20108 through 20109). We added the Vasoactive Medications sub-element to our proposal in order to harmonize the proposed IV Mediciations element with the data currently collected in the LCDS.

If the assessor indicates that the patient is receiving IV medications on the principal IV Medications data element, the assessor would then indicate which types of medications (for example, Antibiotics, Anticoagulants, Vasoactive Medications, Other). An IV Medications data element is currently in use on the MDS in SNFs and there is a related data element in OASIS that collects information on Intravenous and Infusion Therapies. The LCDS in LTCHs currently collects data on IV Vasoactive Medications. We are proposing to modify the existing IV Vasoactive Medications data element in the LCDS to include additional sub-elements included in the standardized form of the IV Medications (Antibiotics, Anticoagulation, Vasoactive Medications, Other) data element and a principal data element for IV Medications. For more information on the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

An IV Medications data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20108 through 20109). In that proposed rule, we stated that the proposal was informed by input we received on Vasoactive Medications through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported this data element, with one noting the importance of this data element in supporting care transitions. We also stated that these commenters had criticized the need for collecting specifically Vasoactive Medications, giving feedback that the data element was too narrowly focused. In addition, public comment received indicated that the clinical significance of vasoactive medications administration alone was not high enough in PAC to merit mandated assessment, noting that related and more useful information could be captured in an item that assessed all IV medication use. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the Special Services, Treatments, and Interventions data elements in general; no additional comments were received that were specific to the IV Medications data element. However, general concerns were expressed about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the IV Medications data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Medications data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Medications data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-*

2014/IMPACT-Act-Downloads-and-Videos.html.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for IV medications, stakeholder input, and strong test results, we are proposing that the IV Medications (Antibiotics, Anticoagulation, Vasoactive Medications, Other) data element with a principal data element and four sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the IV Medications (Antibiotics, Anticoagulation, Vasoactive Medications, Other) data element as standardized patient assessment data for use in the LTCH QRP.

- Transfusions

We are proposing that the Transfusions data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20109 through 20110), transfusion refers to introducing blood or blood products into the circulatory system of a person. Blood transfusions are based on specific protocols, with multiple safety checks and monitoring required during and after the infusion in case of adverse events. Coordination with the provider's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require care coordination and patient monitoring, and impacts planning for transitions of care, as transfusions are not performed by all PAC providers.

The proposed data element consists of the single Transfusions data element. A data element on transfusion is currently in use in the MDS in SNFs (''Transfusions'') and a data element tested in the PAC PRD (''Blood Transfusions'') was found feasible for use in each of the four PAC settings. For more information on the Transfusions data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Transfusions data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20109 through 20110).

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the Special Services, Treatments, and Interventions data elements in general. In response to our proposal, we received comments in support of the Transfusions data element. A commenter supported the inclusion of the Transfusions data element because transfusions are increasingly being performed outside of the hospital setting and reporting transfusions as a SPADE will contribute to higher quality, coordinated care for patients who rely on these life-saving treatments. However, concerns were expressed about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Transfusions data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Transfusions data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Transfusions data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions. Although the TEP did not specifically discuss the Transfusions data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for transfusions, stakeholder input, and strong test results, we are proposing that the Transfusions data element that is currently in use in the MDS in SNFs meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Transfusion data element as standardized patient assessment data for use in the LTCH QRP.

• Dialysis (Hemodialysis, Peritoneal Dialysis)

We are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20110), dialysis is a treatment primarily used to provide replacement for lost kidney function. Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during and following. Patients and residents who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances as well as infections that can lead to sepsis. Further, patients or residents receiving hemodialysis are often transported to a different facility, or at a minimum, to a different location in the same facility for treatment. Close monitoring for fluid shifts, blood pressure abnormalities, and other adverse effects is required prior to, during and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and as with hemodialysis, close monitoring is required.

The proposed data element, Dialysis (Hemodialysis, Peritoneal dialysis) consists of the principal Dialysis data element and two response option sub-elements: Hemodialysis; and Peritoneal dialysis. If the assessor indicates that the patient is receiving dialysis on the principal Dialysis data element, the assessor would then indicate which type (Hemodialysis or Peritoneal dialysis). Dialysis data elements are currently included on the MDS in SNFs and the LCDS in LTCHs and assess the overall use of dialysis. We are proposing to expand the existing Dialysis data element currently in the LCDS to include sub-elements for Hemodialysis and Peritoneal dialysis.

As the result of public feedback described below, in this proposed rule, we are proposing data elements that include the principal Dialysis data element and two sub-elements (Hemodialysis and Peritoneal dialysis). For more information on the Dialysis data elements, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Dialysis data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20110). In that proposed rule, we stated that the proposal was informed by input we received on a singular Hemodialysis data element through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported the assessment of hemodialysis and recommended that the data element be expanded to include peritoneal dialysis. We also noted that several commenters had supported the singular Hemodialysis data element, noting the relevance of this information for sharing across the care continuum to facilitate care coordination and care transitions, the potential for this data element to be used to improve quality, and the feasibility for use in PAC. In addition, we received comment that the item would be useful in improving patient and resident transitions of care. We also noted that several commenters had also stated that peritoneal dialysis should be included in a standardized data element on dialysis and recommended collecting information on peritoneal dialysis in addition to hemodialysis. The rationale for including peritoneal dialysis from commenters included the fact that patients and residents receiving peritoneal dialysis will have different needs at post-acute discharge compared to those receiving hemodialysis or not having any dialysis. Based on these comments, the Hemodialysis data element was expanded to include a principal Dialysis data element and two sub-elements, Hemodialysis and Peritoneal dialysis. We are proposing the version of the Dialysis element that includes two types of dialysis. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received comments in support of the Special Services, Treatments, and Interventions data elements in general. No additional comments were received that were specific to the Dialysis data element. However, concerns were expressed about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Dialysis data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Dialysis data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Dialysis data elements in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/*

IMPACT-Act-Downloads-and-Videos.html.

Taking together the importance of assessing for dialysis, stakeholder input, and strong test results, we are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Dialysis (Hemodialysis, Peritoneal dialysis) data element as standardized patient assessment data for use in the LTCH QRP.

• Intravenous (IV) Access (Peripheral IV, Midline, Central Line)

We are proposing that the IV Access (Peripheral IV, Midline, Central line) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20110 through 20111), patients or residents with central lines, including those peripherally inserted or who have subcutaneous central line ''port'' access, always require vigilant nursing care to keep patency of the lines and ensure that such invasive lines remain free from any potentially life-threatening events such as infection, air embolism, or bleeding from an open lumen. Clinically complex patients and residents are likely to be receiving medications or nutrition intravenously. The sub-elements included in the IV Access data element distinguish between peripheral access and different types of central access. The rationale for distinguishing between a peripheral IV and central IV access is that central lines confer higher risks associated with life-threatening events such as pulmonary embolism, infection, and bleeding.

The proposed data element, IV Access (Peripheral IV, Midline, Central line), consists of the principal IV Access data element and three response option sub-elements: Peripheral IV, Midline, and Central line. The proposed IV Access data element is not currently included on any of the PAC assessment instruments. For more information on the IV Access (Peripheral IV, Midline, Central line) data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

An IV Access data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20110 through 20111). In that proposed rule, we stated that the proposal was informed by input we received on one of the PAC PRD data elements, Central Line Management, a type of IV access, through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the assessment of central line management and recommended that the data element be broadened to also include other types of IV access in addition to central lines. Several commenters supported the data element, noting feasibility and importance for facilitating care coordination and care transitions. However, a few commenters recommended that this data element be broadened to include peripherally inserted central catheters (''PICC lines'') and midline IVs. Based on public comment feedback and in consultation with expert input, we expanded the Central Line Management data element to include more types of IV access (that is, peripheral IV and midline). This expanded version of IV Access is the data element being proposed. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the Special Services, Treatments, and Interventions data elements in general. No additional comments were received that were specific to the IV Access data element. However, concerns were expressed about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the IV Access data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Access data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Access data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for IV access, stakeholder input, and strong test results, we are proposing that the IV access (Peripheral IV, Midline, Central line) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act,

and to adopt the IV access (Peripheral IV, Midline, Central line) data element as standardized patient assessment data for use in the LTCH QRP.

• Nutritional Approach: Parenteral/IV Feeding

We are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20111 through 20112), parenteral nutrition/IV feeding refers to a patient or resident being fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The need for IV/parenteral feeding indicates a clinical complexity that prevents the patient or resident from meeting his or her nutritional needs enterally, and is more resource intensive than other forms of nutrition, as it often requires monitoring of blood chemistries and maintenance of a central line. Therefore, assessing a patient's or resident's need for parenteral feeding is important for care planning and resource use. In addition to the risks associated with central and peripheral intravenous access, total parenteral nutrition is associated with significant risks such as embolism and sepsis.

The proposed data element consists of the single Parenteral/IV Feeding data element. The proposed Parenteral/IV Feeding data element is currently in use in the MDS in SNFs, and equivalent or related data elements are in use in the LCDS, IRF–PAI, and OASIS. We are proposing to replace the existing Total Parenteral Nutrition data element in the LCDS with the proposed Parenteral/IV Feeding data element. For more information on the Parenteral/IV Feeding data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Parenteral/IV Feeding data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20111 through 20112). In that proposed rule, we stated that the proposal was informed by input we received on Total Parenteral Nutrition (an item with nearly the same meaning as the proposed data element, but with the label used in the PAC PRD), through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016, supported this data element, noting its relevance to facilitating care coordination and supporting care transitions. After the public input period, the Total Parenteral Nutrition data element was renamed Parenteral/IV Feeding, to be consistent with how this data element is referred to in the MDS in SNFs. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received comments in support of the Special Services, Treatments, and Interventions data elements in general. In response to our proposal, we received public comments in support of the Parenteral/IV Feeding data element. Several commenters supported the inclusion of nutrition data elements and noted their importance in capturing information on additional resources necessary to treat patients with altered dietary needs. However, one commenter noted limitations of the proposed data elements, such as not recording clinical rationale for nutritional or diet needs. We also received public comments expressing concern about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Parenteral/IV Feeding data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Parenteral/IV Feeding data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Parenteral/IV Feeding data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for parenteral/IV feeding, stakeholder input, and strong test results, we are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Parenteral/IV Feeding data element as standardized patient assessment data for use in the LTCH QRP.

• Nutritional Approach: Feeding Tube

We are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20112), the majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding if unable to eat orally very important in PAC. A feeding tube can be inserted through the nose or the skin on the abdomen to deliver liquid nutrition into the stomach or small intestine. Feeding tubes are resource intensive and, therefore, are important to assess for care planning and resource use. Patients with severe malnutrition are at higher risk for a variety of complications.[715] In PAC settings, there are a variety of reasons that patients and residents may not be able to eat orally (including clinical or cognitive status).

The proposed data element consists of the single Feeding Tube data element. The Feeding Tube data element is currently included in the MDS for SNFs, and in the OASIS for HHAs, where it is labeled Enteral Nutrition. A related data element, collected in the IRF–PAI for IRFs (Tube/Parenteral Feeding), assesses use of both feeding tubes and parenteral nutrition. For more information on the Feeding Tube data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Feeding Tube data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20112). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 on an Enteral Nutrition data element (which is the same as the data element we are proposing in this proposed rule, but is used in the OASIS under a different name) supported the data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions. After the public comment period, the Enteral Nutrition data element used in public comment was renamed ''Feeding Tube'', indicating the presence of an assistive device. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the Special Services, Treatments, and Interventions data elements in general. In response to our proposal, we received public comments in support of the Feeding Tube data element. Several commenters supported the inclusion of nutrition data elements, noting their importance when capturing dietary needs. However, we also received recommendations to increase the specificity of the data element by using more clinical terminology and assessing clinical rationale for nutritional or dietary needs as well as concerns about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Feeding Tube data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Feeding Tube data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Feeding Tube data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for feeding tubes, stakeholder input, and strong test results, we are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Feeding Tube data element as standardized patient assessment data for use in the LTCH QRP.

- Nutritional Approach: Mechanically Altered Diet

We are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20112 through 20113), the Mechanically Altered Diet data element refers to food that has been altered to make it easier for the patient or resident to chew and swallow, and this type of diet is used for patients and residents who have difficulty performing these functions. Patients with severe malnutrition are at higher risk for a variety of complications.[716]

[715] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention modify it?'' *Am J of Clinical Nutrition,* 47(2): 352–356.

[716] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention

In PAC settings, there are a variety of reasons that patients and residents may have impairments related to oral feedings, including clinical or cognitive status. The provision of a mechanically altered diet may be resource intensive, and can signal difficulties associated with swallowing/eating safety, including dysphagia. In other cases, it signifies the type of altered food source, such as ground or puree, that will enable the safe and thorough ingestion of nutritional substances and ensure safe and adequate delivery of nourishment to the patient. Often, patients on mechanically altered diets also require additional nursing supports such as individual feeding, or direct observation, to ensure the safe consumption of the food product. Assessing whether a patient or resident requires a mechanically altered diet is therefore important for care planning and resource identification.

The proposed data element consists of the single Mechanically Altered Diet data element. The proposed data element for a mechanically altered diet is currently included on the MDS for SNFs. A related data element for modified food consistency/supervision is currently included on the IRF–PAI for IRFs. Another related data element is included in the OASIS for HHAs that collects information about independent eating that requires ''a liquid, pureed or ground meat diet.'' For more information on the Mechanically Altered Diet data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Mechanically Altered Diet data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20112 through 20113).

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the Special Services, Treatments, and Interventions data elements in general. In response to our proposal, we received comments in support of the Mechanically Altered Diet data element. Several commenters supported the inclusion of nutrition data elements noting their importance in capturing information on additional resources necessary to treat patients with altered dietary needs. However, one commenter noted limitations of the proposed data elements, such as not recording clinical rationale for nutritional or diet needs. We received further concerns regarding not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Mechanically Altered Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Mechanically Altered Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Mechanically Altered Diet data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for mechanically altered diet, stakeholder input, and strong test results, we are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Mechanically Altered Diet data element as standardized patient assessment data for use in the LTCH QRP.

• Nutritional Approach: Therapeutic Diet

We are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20113), a therapeutic diet refers to meals planned to increase, decrease, or eliminate specific foods or nutrients in a patient or resident's diet, such as a low-salt diet, for the purpose of treating a medical condition. The use of therapeutic diets among patients in PAC provides insight on the clinical complexity of these patients and their multiple comorbidities. Therapeutic diets are less resource intensive from the bedside nursing perspective, but do signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. The communication among PAC providers about whether a patient is receiving a particular therapeutic diet is critical to ensure safe transitions of care.

The proposed data element consists of the single Therapeutic Diet data element. The Therapeutic Diet data element is currently in use in the MDS in SNFs. For more information on the Therapeutic Diet data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-*

modify it?'' *Am J of Clinical Nutrition,* 47(2): 352–356.

2014/IMPACT-Act-Downloads-and-Videos.html.

The Therapeutic Diet data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20113).

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the Special Services, Treatments, and Interventions data elements in general. Several commenters supported the inclusion of nutrition data elements noting their importance in capturing information on additional resources necessary to treat patients with altered dietary needs. However, one commenter noted limitations of the proposed data elements, such as not recording clinical rationale for nutritional or diet needs. Other commenters recommended the addition of specific terminology to these data elements, as well as aligning the definition of Therapeutic Diet with the Academy of Nutrition and Dietetics' definition. One commenter suggested use of the term ''medically altered diet'' instead of ''therapeutic diet.'' We also received comments related to concerns about not having recent, comprehensive field testing of proposed data elements.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Therapeutic Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Therapeutic Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Therapeutic Diet data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions and the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for therapeutic diet, stakeholder input, and strong test results, we are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the Therapeutic Diet data element as standardized patient assessment data for use in the LTCH QRP.

- High-Risk Drug Classes: Use and Indication

We are proposing that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

Most patients receiving PAC services depend on short- and long-term medications to manage their medical conditions. However, as a treatment, medications are not without risk; medications are in fact a leading cause of adverse events. A study by the U.S. Department of Health and Human Services found that 31 percent of adverse events that occurred in 2008 among hospitalized Medicare beneficiaries were related to medication.[717] Moreover, changes in a patient's condition, medications, and transitions between care settings put patients at risk of medication errors and adverse drug events (ADEs). ADEs may be caused by medication errors such as drug omissions, errors in dosage, and errors in dosing frequency.[718]

ADEs are known to occur across different types of healthcare settings. For example, the incidence of ADEs in the outpatient setting has been estimated at 1.15 ADEs per 100 person-months,[719] while the rate of ADEs in the long-term care setting is approximately 9.80 ADEs per 100 resident-months.[720] In the hospital setting, the incidence has been estimated at 15 ADEs per 100 admissions.[721] In addition, approximately half of all hospital-related medication errors and 20 percent of ADEs occur during transitions within, admission to, transfer to, or discharge from a hospital.[722] [723] [724] ADEs are more common among older adults, who make up most patients receiving PAC services. The rate of emergency department visits for ADEs is three times higher among adults 65 years of age and older compared to that among those younger than age 65.[725]

Understanding the types of medication a patient is taking and the

[717] U.S. Department of Health and Human Services. Office of Inspector General. Daniel R. Levinson Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. OEI–06–09–00090. November 2010. Available at: *https://www.oig.hhs.gov/oei/reports/oei-06-09-00090.pdf.*

[718] Boockvar KS, Liu S, Goldstein N, Nebeker J, Siu A, Fried T. Prescribing discrepancies likely to cause adverse drug events after patient transfer. Qual Saf Health Care. 2009;18(1):32–6.

[719] Gandhi TK, Seger AC, Overhage JM, et al. Outpatient adverse drug events identified by screening electronic health records. *J Patient Saf* 2010;6:91–6.doi:10.1097/PTS.0b013e3181dcae06.

[720] Gurwitz JH, Field TS, Judge J, Rochon P, Harrold LR, Cadoret C, et al. The incidence of adverse drug events in two large academic long-term care facilities. *Am J Med.* 2005; 118(3):251±8. Epub 2005/03/05. Available at: *https://doi.org/10.1016/j.amjmed.2004.09.018* PMID: 15745723.

[721] Hug BL, Witkowski DJ, Sox CM, Keohane CA, Seger DL, Yoon C, Matheny ME, Bates DW. Occurrence of adverse, often preventable, events in community hospitals involving nephrotoxic drugs or those excreted by the kidney. Kidney Int. 2009; 76:1192–1198. [PubMed: 19759525].

[722] Barnsteiner JH. Medication reconciliation: transfer of medication information across settings-keeping it free from error. *J Infus Nurs.* 2005;28(2 Suppl):31–36.

[723] Rozich J, Roger, R. Medication safety: one organization's approach to the challenge. *Journal of Clinical Outcomes Management.* 2001(8):27–34.

[724] Gleason KM, Groszek JM, Sullivan C, Rooney D, Barnard C, Noskin GA. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. *Am J Health Syst Pharm.* 2004;61(16):1689–1695.

[725] Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013–2014. *JAMA.* doi: 10.1001/jama.2016.16201.

reason for its use are key facets of a patient's treatment with respect to medication. Some classes of drugs are associated with more risk than others.[726] We are proposing one High-Risk Drug Class data element with six medication classes as sub-elements. The six medication classes we are proposing as response options for the High-Risk Drug Classes: Use and Indication data element are: Anticoagulants; antiplatelets; hypoglycemics (including insulin); opioids; antipsychotics; and antibiotics. These drug classes are high-risk due to the adverse effects that may result from use. In particular, bleeding risk is associated with anticoagulants and antiplatelets; [727] [728] fluid retention, heart failure, and lactic acidosis are associated with hypoglycemics; [729] misuse is associated with opioids; [730] fractures and strokes are associated with antipsychotics; [731] [732] and various adverse events such as central nervous systems effects and gastrointestinal intolerance are associated with antimicrobials,[733] the larger category of medications that include antibiotics. Moreover, some medications in five of the six drug classes included in this data element are included in the 2019 Updated Beers Criteria® list as potentially inappropriate medications for use in older adults.[734] Finally, although a complete medication list should record several important attributes of each medication (for example, dosage, route, stop date), recording an indication for the drug is of crucial importance.[735]

The High-Risk Drug Classes: Use and Indication data element requires an assessor to record whether or not a patient is taking any medications within six drug classes. The six response options for this data element are high-risk drug classes with particular relevance to PAC patients and residents, as identified by our data element contractor. The six data response options are Anticoagulants, Antiplatelets, Hypoglycemics, Opioids, Antipsychotics, and Antibiotics. For each drug class, the assessor is asked to indicate if the patient is taking any medications within the class, and, for drug classes in which medications were being taken, whether indications for all drugs in the class are noted in the medical record. For example, for the response option Anticoagulants, if the assessor indicates that the patient is taking anticoagulant medication, the assessor would then indicate if an indication is recorded in the medication record for the anticoagulant(s).

The High-Risk Drug Classes: Use and Indication data element that is being proposed as a SPADE was developed as part of a larger set of data elements to assess medication reconciliation, the process of obtaining a patient's multiple medication lists and reconciling any discrepancies. For more information on the High-Risk Drug Classes: Use and Indication data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We sought public input on the relevance of conducting assessments on medication reconciliation and specifically on the proposed High-Risk Drug Classes: Use and Indication data element. Our data element contractor presented data elements related to medication reconciliation to the TEP convened on April 6 and 7, 2016. The TEP supported a focus on high-risk drugs, because of higher potential for harm to patients and residents, and were in favor of a data element to capture whether or not indications for medications were recorded in the medical record. A summary of the April 6 and 7, 2016 TEP meeting titled ''SPADE Technical Expert Panel Summary (First Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* Medication reconciliation data elements were also discussed at a second TEP meeting on January 5 and 6, 2017, convened by our data element contractor. At this meeting, the TEP agreed about the importance of evaluating the medication reconciliation process, but disagreed about how this could be accomplished through standardized assessment. The TEP also disagreed about the usability and appropriateness of using the Beers Criteria to identify high-risk medications.[736] A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also solicited public input on data elements related to medication reconciliation during a public input period from April 26 to June 26, 2017. Several commenters expressed support for the medication reconciliation data elements that were put on display, noting the importance of medication reconciliation in preventing medication errors and stated that the items seemed feasible and clinically useful. A few commenters were critical of the choice of 10 drug classes posted during that comment period, arguing that ADEs are not limited to high-risk drugs, and raised issues related to training assessors to correctly complete a valid assessment of medication reconciliation. A summary report for the April 26 to June 26, 2017 public comment period titled ''SPADE May–June 2017 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The High-Risk Drug Classes: Use and Indication data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to

[726] Ibid.

[727] Shoeb M, Fang MC. Assessing bleeding risk in patients taking anticoagulants. *J Thromb Thrombolysis.* 2013;35(3):312–319. doi: 10.1007/s11239–013–0899–7.

[728] Melkonian M, Jarzebowski W, Pautas E. Bleeding risk of antiplatelet drugs compared with oral anticoagulants in older patients with atrial fibrillation: a systematic review and meta-analysis. *J Thromb Haemost.* 2017;15:1500–1510. DOI: 10.1111/jth.13697.

[729] Hamnvik OP, McMahon GT. Balancing Risk and Benefit with Oral Hypoglycemic Drugs. *The Mount Sinai journal of medicine,* New York. 2009; 76:234–243.

[730] Naples JG, Gellad WF, Hanlon JT. The Role of Opioid Analgesics in Geriatric Pain Management. *Clin Geriatr Med.* 2016;32(4):725–735.

[731] Rigler SK, Shireman TI, Cook-Wiens GJ, Ellerbeck EF, Whittle JC, Mehr DR, Mahnken JD. Fracture risk in nursing home residents initiating antipsychotic medications. *J Am Geriatr Soc.* 2013; 61(5):715–722. [PubMed: 23590366].

[732] Wang S, Linkletter C, Dore D et al. Age, antipsychotics, and the risk of ischemic stroke in the Veterans Health Administration. *Stroke* 2012;43:28–31. doi:10.1161/STROKEAHA.111.617191.

[733] Faulkner CM, Cox HL, Williamson JC. Unique aspects of antimicrobial use in older adults. *Clin Infect Dis.* 2005;40(7):997–1004.

[734] American Geriatrics Society 2015 Beers Criteria Update Expert Panel. American Geriatrics Society. Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2015; 63:2227–2246.

[735] Li Y, Salmasian H, Harpaz R, Chase H, Friedman C. Determining the reasons for medication prescriptions in the EHR using knowledge and natural language processing. AMIA Annu Symp Proc. 2011;2011:768–76.

[736] American Geriatrics Society 2015 Beers Criteria Update Expert Panel. American Geriatrics Society. Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2015; 63:2227–2246.

August 2018. Results of this test found the High-Risk Drug Classes: Use and Indication data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the High-Risk Drug Classes: Use and Indication data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In, addition, our contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the standardized patient assessment data elements. The TEP acknowledged the challenges of assessing medication safety, but was supportive of some of the data elements focused on medication reconciliation that were tested in the National Beta Test. The TEP was especially supportive of the focus on the six high-risk drug classes and using these classes to assess whether the indication for a drug is recorded. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. These activities provided updates on the field-testing work and solicited feedback on data elements considered for standardization, including the High-Risk Drug Classes: Use and Indication data element. One stakeholder group was critical of the six drug classes included as response options in the High-Risk Drug Classes: Use and Indication data element, noting that potentially risky medications (for example, muscle relaxants) are not included in this list; that there may be important differences between drugs within classes (for example, more recent versus older style antidepressants); and that drug allergy information is not captured. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. In addition, one commenter questioned whether the time to complete the High-Risk Drug Classes: Use and Indication data element would differ across settings. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for the use and having indications recorded for high-risk drugs, stakeholder input, and strong test results, we are proposing that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act, and to adopt the High-Risk Drug Classes: Use and Indication data element as standardized patient assessment data for use in the LTCH QRP.

d. Medical Condition and Comorbidity Data

Assessing medical conditions and comorbidities is critically important for care planning and safety for patients and residents receiving PAC services, and the standardized assessment of selected medical conditions and comorbidities across PAC providers is important for managing care transitions and understanding medical complexity.

Below we discuss our proposals for data elements related to the medical condition of pain as standardized patient assessment data. Appropriate pain management begins with a standardized assessment, and thereafter establishing and implementing an overall plan of care that is person-centered, multi-modal, and includes the treatment team and the patient. Assessing and documenting the effect of pain on sleep, participation in therapy, and other activities may provide information on undiagnosed conditions and comorbidities and the level of care required, and do so more objectively than subjective numerical scores. With that, we assess that taken separately and together, these proposed data elements are essential for care planning, consistency across transitions of care, and identifying medical complexities including undiagnosed conditions. We also conclude that it is the standard of care to always consider the risks and benefits associated with a personalized care plan, including the risks of any pharmacological therapy, especially opioids.[737] We also conclude that in addition to assessing and appropriately treating pain through the optimum mix of pharmacologic, non-pharmacologic, and alternative therapies, while being cognizant of current prescribing guidelines, clinicians in partnership with patients are best able to mitigate factors that contribute to the current opioid crisis.[738] [739] [740]

In alignment with our Meaningful Measures Initiative, accurate assessment of medical conditions and comorbidities of patients and residents in PAC is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. The SPADEs will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care through: Facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing medical conditions and comorbidities are needed in order to initiate a management program that can optimize a patient or resident's prognosis and reduce the possibility of adverse events.

[737] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[738] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[739] Fishman SM, Carr DB, Hogans B, et al. Scope and Nature of Pain- and Analgesia-Related Content of the United States Medical Licensing Examination (USMLE). *Pain Med Malden Mass.* 2018;19(3):449–459. doi:10.1093/pm/pnx336.

[740] Fishman SM, Young HM, Lucas Arwood E, et al. Core competencies for pain management: results of an interprofessional consensus summit. Pain Med Malden Mass. 2013;14(7):971–981. doi:10.1111/pme.12107.

We are inviting comment that apply specifically to the standardized patient assessment data for the category of medical conditions and comorbidities, specifically on:

- Pain Interference (Pain Effect on Sleep, Pain Interference With Therapy Activities, and Pain Interference With Day-to-Day Activities)

In acknowledgement of the opioid crisis, we specifically are seeking comment on whether or not we should add these pain items in light of those concerns. Commenters should address to what extent the collection of the SPADES described below through patient queries might encourage providers to prescribe opioids.

We are proposing that a set of three data elements on the topic of Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical condition and comorbidity data under section 1899B(b)(1)(B)(iv) of the Act.

The practice of pain management began to undergo significant changes in the 1990s because the inadequate, non-standardized, non-evidence-based assessment and treatment of pain became a public health issue.[741] In pain management, a critical part of providing comprehensive care is performance of a thorough initial evaluation, including assessment of both the medical and any biopsychosocial factors causing or contributing to the pain, with a treatment plan to address the causes of pain and to manage pain that persists over time.[742] Quality pain management, based on current guidelines and evidence-based practices, can minimize unnecessary opioid prescribing both by offering alternatives or supplemental treatment to opioids and by clearly stating when they may be appropriate, and how to utilize risk-benefit analysis for opioid and non-opioid treatment modalities.[743]

Pain is not a surprising symptom in PAC patients and residents, where healing, recovery, and rehabilitation often require regaining mobility and other functions after an acute event. Standardized assessment of pain that interferes with function is an important first step towards appropriate pain management in PAC settings. The National Pain Strategy called for refined assessment items on the topic of pain, and describes the need for these improved measures to be implemented in PAC assessments.[744] Further, the focus on pain *interference,* as opposed to pain intensity or pain frequency, was supported by the TEP convened by our data element contractor as an appropriate and actionable metric for assessing pain. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We appreciate the important concerns related to the misuse and overuse of opioids in the treatment of pain and to that end we note that in this proposed rule we have also proposed a SPADE that assesses for the use of, as well as importantly the indication for that use of, high risk drugs, including opioids. Further, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57193), we adopted the Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) measure which assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s), which includes issues associated with use and misuse of opioids for pain management, when such issues were identified.

We also note that the proposed SPADE related to pain assessment are not associated with any particular approach to management. Since the use of opioids is associated with serious complications, particularly in the elderly,[745] [746] [747] an array of successful non-pharmacologic and non-opioid approaches to pain management may be considered. PAC providers have historically used a range of pain management strategies, including non-steroidal anti-inflammatory drugs, ice, transcutaneous electrical nerve stimulation (TENS) therapy, supportive devices, acupuncture, and the like. In addition, non-pharmacological interventions for pain management include, but are not limited to, biofeedback, application of heat/cold, massage, physical therapy, nerve block, stretching and strengthening exercises, chiropractic, electrical stimulation, radiotherapy, and ultrasound.[748] [749] [750]

We believe that standardized assessment of pain interference will support PAC clinicians in applying best-practices in pain management for chronic and acute pain, consistent with current clinical guidelines. For example, the standardized assessment of both opioids and pain interference would support providers in successfully tapering patients/residents who arrive in the PAC setting with long-term opioid use off of opioids onto non-pharmacologic treatments and non-opioid medications, as recommended by the Society for Post-Acute and Long-Term Care Medicine,[751] and consistent with HHS' 5-Point Strategy To Combat the Opioid Crisis [752] which includes ''Better Pain Management.''

The Pain Interference data element set consists of three data elements: Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities. Pain Effect on Sleep assesses the frequency with which pain effects a patient's sleep. Pain Interference with Therapy Activities assesses the frequency with which pain interferes with a patient's ability to participate in therapies. Pain Interference with Day-to-Day Activities assesses the extent to

[741] Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.* Washington (DC): National Academies Press (US); 2011. *http://www.ncbi.nlm.nih.gov/books/NBK91497/.*

[742] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[743] National Academies. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use.* Washington DC: National Academies of Sciences, Engineering, and Medicine.; 2017.

[744] National Pain Strategy: A Comprehensive Population-Health Level Strategy for Pain. Available at: *https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf.*

[745] Chau, D.L., Walker, V., Pai, L., & Cho, L.M. (2008). Opiates and elderly: use and side effects. *Clinical interventions in aging, 3*(2), 273–8.

[746] Fine, P.G. (2009). Chronic Pain Management in Older Adults: Special Considerations. *Journal of Pain and Symptom Management,* 38(2): S4–S14.

[747] Solomon, D.H., Rassen, J.A., Glynn, R.J., Garneau, K., Levin, R., Lee, J., & Schneeweiss, S.. (2010). *Archives Internal Medicine,* 170(22):1979–1986.

[748] Byrd L. Managing chronic pain in older adults: a long-term care perspective. *Annals of Long-Term Care: Clinical Care and Aging.* 2013;21(12):34–40.

[749] Kligler, B., Bair, M.J., Banerjea, R. et al. (2018). Clinical Policy Recommendations from the VHA State-of-the-Art Conference on Non-Pharmacological Approaches to Chronic Musculoskeletal Pain. *Journal of General Internal Medicine, 33*(Suppl 1): 16. *https://doi.org/10.1007/s11606-018-4323-z.*

[750] Chou, R., Deyo, R., Friedly, J., et al. (2017). Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. *Annals of Internal Medicine, 166*(7):493–505.

[751] Society for Post-Acute and Long-Term Care Medicine (AMDA). (2018). Opioids in Nursing Homes: Position Statement. Available at: *https://paltc.org/opioids%20in%20nursing%20homes.*

[752] *https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html.*

which pain interferes with a patient's ability to participate in day-to-day activities excluding therapy.

A similar data element on the effect of pain on activities is currently included in the OASIS. A similar data element on the effect on sleep is currently included in the MDS instrument. For more information on the Pain Interference data elements, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We sought public input on the relevance of conducting assessments on pain and specifically on the larger set of Pain Interview data elements included in the National Beta Test. The proposed data elements were supported by comments from the TEP meeting held by our data element contractor on April 7 to 8, 2016. The TEP affirmed the feasibility and clinical utility of pain as a concept in a standardized assessment. The TEP agreed that data elements on pain interference with ability to participate in therapies versus other activities should be addressed. Further, during a more recent convening of the same TEP on September 17, 2018, the TEP supported the interview-based pain data elements included in the National Beta Test. The TEP members were particularly supportive of the items that focused on how pain interferes with activities (that is, Pain Interference data elements), because understanding the extent to which pain interferes with function would enable clinicians to determine the need for appropriate pain treatment. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We held a public input period in 2016 to solicit feedback on the standardization of pain and several other items that were under development in prior efforts. From the prior public comment period, we included several pain data elements (Pain Effect on Sleep; Pain Interference—Therapy Activities; Pain Interference—Other Activities) in a second call for public input, open from April 26 to June 26, 2017. The items we sought comment on were modified from all stakeholder and test efforts. Commenters provided general comments about pain assessment in general in addition to feedback on the specific pain items. A few commenters shared their support for assessing pain, the potential for pain assessment to improve the quality of care, and for the validity and reliability of the data elements. Commenters affirmed that the item of pain and the effect on sleep would be suitable for PAC settings. Commenters' main concerns included redundancy with existing data elements, feasibility and utility for cross-setting use, and the applicability of interview-based items to patients and residents with cognitive or communication impairments, and deficits. A summary report for the April 26 to June 26, 2017 public comment period titled ''SPADE May–June 2017 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Pain Interference data elements were included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Pain Interference data elements to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Pain Interference data elements in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. In addition, one commenter expressed strong support for the Pain data elements and was encouraged by the fact that this portion of the assessment goes beyond merely measuring the presence of pain. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for the effect of pain on function, stakeholder input, and strong test results, we are proposing that the three data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) that comprise the set of Pain Interference data elements meet the definition of standardized patient assessment data with respect to medical conditions and comorbidities under section 1899B(b)(1)(B)(iv) of the Act, and to adopt the Pain Interference data elements as standardized patient assessment data for use in the LTCH QRP.

e. Impairment Data

Hearing and vision impairments are conditions that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess, accommodate, and treat these conditions increases the likelihood that patients will require more intensive and prolonged treatment. Onset of these conditions can be gradual, so individualized assessment with accurate screening tools and follow-up evaluations are essential to determining which patients need hearing- or vision-specific medical attention or assistive devices and accommodations, including auxiliary aids and/or services, and to ensure that person-directed care plans are developed to accommodate a patient's or resident's needs. Accurate diagnosis and management of hearing or vision impairment would likely improve rehabilitation outcomes and care transitions, including transition from institutional-based care to the community. Accurate assessment of hearing and vision impairment would be expected to lead to appropriate treatment, accommodations, including

the provision of auxiliary aids and services during the stay, and ensure that patients continue to have their vision and hearing needs met when they leave the facility.

In alignment with our Meaningful Measures Initiative, we expect accurate individualized assessment, treatment, and accommodation of hearing and vision impairments of patients and residents in PAC to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. For example, standardized assessment of hearing and vision impairments used in PAC will support ensuring patient safety (for example, risk of falls), identifying accommodations needed during the stay, and appropriate support needs at the time of discharge or transfer. Standardized assessment of these data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care (for example, facilitating better care continuity and coordination); better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing hearing and vision impairments are needed to initiate a management program that can optimize a patient or resident's prognosis and reduce the possibility of adverse events.

- Hearing

We are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments data under section 1899B(b)(1)(B)(v) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20114 through 20115), accurate assessment of hearing impairment is important in the PAC setting for care planning and resource use. Hearing impairment has been associated with lower quality of life, including poorer physical, mental, and social functioning, and emotional health.[753] [754] Treatment and accommodation of hearing impairment led to improved health outcomes, including but not limited to quality of life.[755] For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,[756] [757] [758] higher rates of incident cognitive impairment and cognitive decline,[759] and less time in occupational therapy.[760] Accurate assessment of hearing impairment is important in the PAC setting for care planning and defining resource use.

The proposed data element consists of the single Hearing data element. This data consists of one question that assesses level of hearing impairment. This data element is currently in use in the MDS in SNFs. For more information on the Hearing data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Hearing data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20114 through 20115). In that proposed rule, we stated that the proposal was informed by input we received on the PAC PRD form of the data element (''Ability to Hear'') through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 recommended that hearing, vision, and communication assessments be administered at the beginning of patient assessment process. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received public comments in support of the Hearing data element as well as concerns about not having recent, comprehensive field testing of proposed data elements. Commenters were supportive of adopting the Hearing data element for standardized cross-setting use, noting that it would help address the needs of patient and residents with disabilities and that failing to identify impairments during the initial assessment can result in inaccurate diagnoses of impaired language or cognition and can invalidate other information obtained from patient assessment.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed rule, the Hearing data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Hearing data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Hearing data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs, including the Hearing data element. The TEP affirmed the importance of standardized assessment of hearing impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing

[753] Dalton DS, Cruickshanks KJ, Klein BE, Klein R, Wiley TL, Nondahl DM. The impact of hearing loss on quality of life in older adults. *Gerontologist.* 2003;43(5):661–668.

[754] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[755] Horn KL, McMahon NB, McMahon DC, Lewis JS, Barker M, Gherini S. Functional use of the Nucleus 22-channel cochlear implant in the elderly. *The Laryngoscope.* 1991;101(3):284–288.

[756] Sprinzl GM, Riechelmann H. Current trends in treating hearing loss in elderly people: A review of the technology and treatment options—a mini-review. *Gerontology.* 2010;56(3):351–358.

[757] Lin FR, Thorpe R, Gordon-Salant S, Ferrucci L. Hearing Loss Prevalence and Risk Factors Among Older Adults in the United States. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences.* 2011;66A(5):582–590.

[758] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[759] Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. Hearing Loss and Incident Dementia. *Arch Neurol.* 2011;68(2):214–220.

[760] Cimarolli VR, Jung S. Intensity of Occupational Therapy Utilization in Nursing Home Residents: The Role of Sensory Impairments. *J Am Med Dir Assoc.* 2016;17(10):939–942.

SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. In addition, a commenter expressed support for the Hearing data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for hearing, stakeholder input, and strong test results, we are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act, and to adopt the Hearing data element as standardized patient assessment data for use in the LTCH QRP.

- Vision

We are proposing that the Vision data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act.

As described in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20115 through 20116), evaluation of an individual's ability to see is important for assessing for risks such as falls and provides opportunities for improvement through treatment and the provision of accommodations, including auxiliary aids and services, which can safeguard patients and improve their overall quality of life. Further, vision impairment is often a treatable risk factor associated with adverse events and poor quality of life. For example, individuals with visual impairment are more likely to experience falls and hip fracture, have less mobility, and report depressive symptoms.[761] [762] [763] [764] [765] [766] [767] Individualized initial screening can lead to life-improving interventions such as accommodations, including the provision of auxiliary aids and services, during the stay and/or treatments that can improve vision and prevent or slow further vision loss. In addition, vision impairment is often a treatable risk factor associated with adverse events which can be prevented and accommodated during the stay. Accurate assessment of vision impairment is important in the LTCH setting for care planning and defining resource use.

The proposed data element consists of the single Vision data element (Ability To See in Adequate Light) that consists of one question with five response categories. The Vision data element that we are proposing for standardization was tested as part of the development of the MDS and is currently in use in that assessment in SNFs. Similar data elements, but with different wording and fewer response option categories, are in use in the OASIS. For more information on the Vision data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Vision data element was first proposed as a SPADE in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20115 through 20116). In that proposed rule, we stated that the proposal was informed by input we received on the Ability to See in Adequate Light data element (version tested in the PAC PRD with three response categories) through a call for input published on the CMS Measures Management System Blueprint website. Although the data element on which we solicited input differed from the proposed data element, input submitted from August 12 to September 12, 2016 supported the assessment of vision in PAC settings and the useful information such a vision data element would provide. The commenters stated that the Ability to See item would provide important information that would facilitate care coordination and care planning, and consequently improve the quality of care. Other commenters suggested it would be helpful as an indicator of resource use and noted that the item would provide useful information about the abilities of patients and residents to care for themselves. Additional commenters noted that the item could feasibly be implemented across PAC providers and that its kappa scores from the PAC PRD support its validity. Some commenters noted a preference for MDS version of the Vision data element over the form put forward in public comment, citing the widespread use of this data element. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IPPS/LTCH PPS proposed rule, we received comments in support of the Vision data element as well as concerns about not having recent, comprehensive field testing of proposed data elements. Commenters supported addressing the needs of persons with disabilities and noted the importance of the Vision data element because unaddressed impairments during the initial assessment can result in inaccurate diagnoses of impaired language or cognition and can invalidate other information obtained from the patient assessment. Commenters recommended that hearing, vision, and communication assessments be administered at the beginning of the patient assessment process. One commenter expressed concern that the Ability to See data element would not capture all aspects of functional vision—that is, the person's ability to use vision to complete daily activities and participate in environments—because it fails to assess visual field and low contract visual acuity.

Subsequent to receiving comments on the FY 2018 IPPS/LTCH PPS proposed

[761] Colon-Emeric CS, Biggs DP, Schenck AP, Lyles KW. Risk factors for hip fracture in skilled nursing facilities: who should be evaluated? *Osteoporos Int.* 2003;14(6):484–489.

[762] Freeman EE, Munoz B, Rubin G, West SK. Visual field loss increases the risk of falls in older adults: the Salisbury eye evaluation. *Invest Ophthalmol Vis Sci.* 2007;48(10):4445–4450.

[763] Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh.* 2004;36(1):79–85.

[764] Nguyen HT, Black SA, Ray LA, Espino DV, Markides KS. Predictors of decline in MMSE scores among older Mexican Americans. *J Gerontol A Biol Sci Med Sci.* 2002;57(3):M181–185.

[765] Prager AJ, Liebmann JM, Cioffi GA, Blumberg DM. Self-reported Function, Health Resource Use, and Total Health Care Costs Among Medicare Beneficiaries With Glaucoma. *JAMA ophthalmology.* 2016;134(4):357–365.

[766] Rovner BW, Ganguli M. Depression and disability associated with impaired vision: the MoVies Project. *J Am Geriatr Soc.* 1998;46(5):617–619.

[767] Tinetti ME, Ginter SF. The nursing home life-space diameter. A measure of extent and frequency of mobility among nursing home residents. *J Am Geriatr Soc.* 1990;38(12):1311–1315.

rule, the Vision data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Vision data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Vision data element in the National Beta Test can be found in the document titled ''Proposed Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs, including the Vision data element. The TEP affirmed the importance of standardized assessment of vision impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. In addition, a commenter expressed support for the Vision data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for vision, stakeholder input, and strong test results, we are proposing that the Vision data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act, and to adopt the Vision data element as standardized patient assessment data for use in the LTCH QRP.

f. Proposed New Category: Social Determinants of Health

(1) Proposed Social Determinants of Health Data Collection To Inform Measures and Other Purposes

Subparagraph (A) of section 2(d)(2) of the IMPACT Act requires CMS to assess appropriate adjustments to quality measures, resource measures, and other measures, and to assess and implement appropriate adjustments to payment under Medicare, based on those measures, after taking into account studies conducted by ASPE on social risk factors (described below) and other information, and based on an individual's health status and other factors. Subparagraph (C) of section 2(d)(2) of the IMPACT Act further requires the Secretary to carry out periodic analyses, at least every 3 years, based on the factors referred to subparagraph (A) so as to monitor changes in possible relationships. Subparagraph (B) of section 2(d)(2) of the IMPACT Act requires CMS to collect or otherwise obtain access to data necessary to carry out the requirement of the paragraph (both assessing adjustments described above in such subparagraph (A) and for periodic analyses in such subparagraph (C)). Accordingly we are proposing to use our authority under subparagraph (B) of section 2(d)(2) of the IMPACT Act to establish a new data source for information to meet the requirements of subparagraphs (A) and (C) of section 2(d)(2) of the IMPACT Act. In this rule, we are proposing to collect and access data about social determinants of health (SDOH) to perform CMS' responsibilities under subparagraphs (A) and (C) of section 2(d)(2) of the IMPACT Act, as explained in more detail below. Social determinants of health, also known as social risk factors, or health-related social needs, are the socioeconomic, cultural and environmental circumstances in which individuals live that impact their health. We are proposing to collect information on seven proposed SDOH SPADE data elements relating to race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation; a detailed discussion of each of the proposed SDOH data elements is found in section VIII.C.7.f.(2) of the preamble of this proposed rule.

We are also proposing to use the assessment instrument for the LTCH QRP, the LCDS, described as a PAC assessment instrument under section 1899B(a)(2)(B) of the Act, to collect these data via an existing data collection mechanism. We believe this approach will provide CMS with access to data with respect to the requirements of section 2(d)(2) of the IMPACT Act, while minimizing the reporting burden on PAC health care providers by relying on a data reporting mechanism already used and an existing system to which PAC health care providers are already accustomed.

The IMPACT Act includes several requirements applicable to the Secretary, in addition to those imposing new data reporting obligations on certain PAC providers as discussed in section VIII.C.7.f.(2) of the preamble of this proposed rule. Subparagraphs (A) and (B) of section 2(d)(1) of the IMPACT Act require the Secretary, acting through the Office of the Assistant Secretary for Planning and Evaluation (ASPE), to conduct two studies that examine the effect of risk factors, including individuals' socioeconomic status, on quality, resource use and other measures under the Medicare program. The first ASPE study was completed in December 2016 and is discussed below, and the second study is to be completed in the fall of 2019. We recognize that ASPE, in its studies, is considering a broader range of social risk factors than the SDOH data elements in this proposal, and address both PAC and non-PAC settings. We acknowledge that other data elements may be useful to understand, and that some of those elements may be of particular interest in non-PAC settings. For example, for beneficiaries receiving care in the community, as opposed to an in-patient facility, housing stability and food insecurity may be more relevant. We will continue to take into account the findings from both of ASPE's reports in future policy making.

One of the ASPE's first actions under the IMPACT Act was to commission the National Academies of Sciences, Engineering, and Medicine (NASEM) to define and conceptualize socioeconomic status for the purposes of ASPE's two studies under section 2(d)(1) of the IMPACT Act. The NASEM convened a panel of experts in the field and conducted an extensive literature

review. Based on the information collected, the 2016 NASEM panel report titled, ''Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors,'' concluded that the best way to assess how social processes and social relationships influence key health-related outcomes in Medicare beneficiaries is through a framework of social risk factors instead of socioeconomic status. Social risk factors discussed in the NASEM report include socioeconomic position, race, ethnicity, gender, social context, and community context. These factors are discussed at length in chapter 2 of the NASEM report, titled ''Social Risk Factors.'' [768] Consequently NASEM framed the results of its report in terms of ''social risk factors'' rather than ''socioeconomic status'' or ''sociodemographic status.'' The full text of the ''Social Risk Factors'' NASEM report is available for reading on the website at: *https://www.nap.edu/read/21858/chapter/1.*

Each of the data elements we are proposing to collect and access pursuant to our authority under section 2(d)(2)(B) of the IMPACT Act is identified in the 2016 NASEM report as a social risk factor that has been shown to impact care use, cost and outcomes for Medicare beneficiaries. CMS uses the term social determinants of health (SDOH) to denote social risk factors, which is consistent with the objectives of Healthy People 2020.[769]

ASPE issued its first Report to Congress, titled ''Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs,'' under section 2(d)(1)(A) of the IMPACT Act on December 21, 2016.[770] Using NASEM's social risk factors framework, ASPE focused on the following social risk factors, in addition to disability: (1) Dual enrollment in Medicare and Medicaid as a marker for low income, (2) residence in a low-income area, (3) Black race, (4) Hispanic ethnicity, and; (5) residence in a rural area. ASPE acknowledged that the social risk factors examined in its report were limited due to data availability. The report also noted that the data necessary to meaningfully attempt to reduce disparities and identify and reward improved outcomes for beneficiaries with social risk factors have not been collected consistently on a national level in post-acute care settings. Where these data have been collected, the collection frequently involves lengthy questionnaires. More information on the Report to Congress on Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs, including the full report, is available on the website at: *https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs-reports.*

Section 2(d)(2) of the IMPACT Act relates to CMS activities and imposes several responsibilities on the Secretary relating to quality, resource use, and other measures under Medicare. As mentioned previously, under subparagraph (A) of section 2(d)(2) of the IMPACT Act, the Secretary is required, on an ongoing basis, taking into account the ASPE studies and other information, and based on an individual's health status and other factors, to assess appropriate adjustments to quality, resource use, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. Section 2(d)(2)(A)(i) of the IMPACT Act applies to measures adopted under subsections (c) and (d) of section 1899B of the Act and to other measures under Medicare. However, CMS' ability to perform these analyses, and assess and make appropriate adjustments is hindered by limits of existing data collections on SDOH data elements for Medicare beneficiaries. In its first study in 2016, in discussing the second study, ASPE noted that information relating to many of the specific factors listed in the IMPACT Act, such as health literacy, limited English proficiency, and Medicare beneficiary activation, are not available in Medicare data.

Subparagraph 2(d)(2)(A) of the IMPACT Act specifically requires the Secretary to take the studies and considerations from ASPE's reports to Congress, as well as other information as appropriate, into account in assessing and implementing adjustments to measures and related payments based on measures in Medicare. The results of the ASPE's first study demonstrated that Medicare beneficiaries with social risk factors tended to have worse outcomes on many quality measures, and providers who treated a disproportionate share of beneficiaries with social risk factors tended to have worse performance on quality measures. As a result of these findings, ASPE suggested a three-pronged strategy to guide the development of value-based payment programs under which all Medicare beneficiaries receive the highest quality healthcare services possible.

The three components of this strategy are to: (1) Measure and report quality of care for beneficiaries with social risk factors; (2) set high, fair quality standards for care provided to all beneficiaries; and (3) reward and support better outcomes for beneficiaries with social risk factors. In discussing how measuring and reporting quality for beneficiaries with social risk factors can be applied to Medicare quality payment programs, the report offered nine considerations across the three-pronged strategy, including enhancing data collection and developing statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

Congress, in section 2(d)(2)(B) of the IMPACT Act, required the Secretary to collect or otherwise obtain access to the data necessary to carry out the provisions of paragraph (2) of section 2(d)of the IMPACT Act through both new and existing data sources. Taking into consideration NASEM's conceptual framework for social risk factors discussed above, ASPE's study, considerations under section 2(d)(1)(A) of the IMPACT Act, as well as the current data constraints of ASPE's first study and its suggested considerations, we are proposing to collect and access data about SDOH under section 2(d)(2) of the IMPACT Act. Our collection and use of the SDOH data described in section VIII.C.7.f.(1) of the preamble of this proposed rule, under section 2(d)(2) of the IMPACT Act, would be independent of our proposal below (in section VIII.C.7.f.(2) of the preamble of this proposed rule) and our authority to require submission of that data for use as SPADE under section 1899B(a)(1)(B) of the Act.

Accessing standardized data relating to the SDOH data elements on a national level is necessary to permit CMS to conduct periodic analyses, to assess appropriate adjustments to quality measures, resource use measures, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. We agree with ASPE's observations, in the value-based purchasing context, that the ability to measure and track quality, outcomes, and costs for beneficiaries with social

[768] National Academies of Sciences, Engineering, and Medicine. 2016. *Accounting for social risk factors in Medicare payment: Identifying social risk factors.* Chapter 2. Washington, DC: The National Academies Press.

[769] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.* (February 2019).

[770] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Payment Programs. Washington, DC.

risk factors over time is critical as policymakers and providers seek to reduce disparities and improve care for these groups. Collecting the data as proposed will provide the basis for our periodic analyses of the relationship between an individual's health status and other factors and quality, resource use, and other measures, as required by section 2(d)(2) of the IMPACT Act, and to assess appropriate adjustments. These data will also permit us to develop the statistical tools necessary to maximize the value of Medicare data, reduce costs and improve the quality of care for all beneficiaries. Collecting and accessing SDOH data in this way also supports the three-part strategy put forth in the first ASPE report, specifically ASPE's consideration to enhance data collection and develop statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

For the reasons discussed above, we are proposing under section 2(d)(2) of the IMPACT Act, to collect the data on the following SDOH: (1) Race, as described in section VIII.C.7.f.(2)(a) of the preamble of this proposed rule; (2) Ethnicity, as described in section VIII.C.7.f.(2)(a) of the preamble of this proposed rule; (3) Preferred Language, as described in section VIII.C.7.f.(2)(b) of the preamble of this proposed rule; (4) Interpreter Services as described in section VIII.C.7.f.(2)(b) of the preamble of this proposed rule; (5) Health Literacy, as described in section VIII.C.7.f.(2)(c) of the preamble of this proposed rule; (6) Transportation, as described in section VIII.C.7.f.(2)(d) of the preamble of this proposed rule; and (7) Social Isolation, as described in section VIII.C.7.f.(2)(e) of the preamble of this proposed rule. These data elements are discussed in more detail below in section VIII.C.7.f.(2) of the preamble of this proposed rule. We welcome comment on this proposal.

(2) Standardized Patient Assessment Data

Section 1899B(b)(1)(B)(vi) of the Act authorizes the Secretary to collect SPADEs with respect to other categories deemed necessary and appropriate. Below we are proposing to create a Social Determinants of Health SPADE category under section 1899B(b)(1)(B)(vi) of the Act. In addition to collecting SDOH data for the purposes outlined above under section 2(d)(2)(B) of the IMPACT Act, we are also proposing to collect as SPADE these same data elements (race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation) under section 1899B(b)(1)(B)(vi) of the Act. We believe that this proposed new category of Social Determinants of Health will inform provider understanding of individual patient risk factors and treatment preferences, facilitate coordinated care and care planning, and improve patient outcomes. We are proposing to deem this category necessary and appropriate, for the purposes of SPADE, because using common standards and definitions for PAC data elements is important in ensuring interoperable exchange of longitudinal information between PAC providers and other providers to facilitate coordinated care, continuity in care planning, and the discharge planning process from post-acute care settings.

All of the Social Determinants of Health data elements we are proposing under section 1899B(b)(1)(B)(vi) of the Act have the capacity to take into account treatment preferences and care goals of patients and to inform our understanding of patient complexity and risk factors that may affect care outcomes. While acknowledging the existence and importance of additional SDOH, we are proposing to assess some of the factors relevant for patients receiving post-acute care that PAC settings are in a position to impact through the provision of services and supports, such as connecting patients with identified needs with transportation programs, certified interpreters, or social support programs.

As previously mentioned, and described in more detail below, we are proposing to adopt the following seven data elements as SPADE under the proposed Social Determinants of Health category: Race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation. To select these data elements, we reviewed the research literature, a number of validated assessment tools and frameworks for addressing SDOH currently in use (for example, Health Leads, NASEM, Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE), and ICD–10), and we engaged in discussions with stakeholders. We also prioritized balancing the reporting burden for PAC providers with our policy objective to collect SPADEs that will inform care planning and coordination and quality improvement across care settings. Furthermore, incorporating SDOH data elements into care planning has the potential to reduce readmissions and help beneficiaries achieve and maintain their health goals.

We also considered feedback received during a listening session that we held on December 13, 2018. The purpose of the listening session was to solicit feedback from health systems, research organizations, advocacy organizations and state agencies, and other members of the public on collecting patient-level data on SDOH across care settings, including consideration of race, ethnicity, spoken language, health literacy, social isolation, transportation, sex, gender identity, and sexual orientation. We also gave participants an option to submit written comments. A full summary of the listening session, titled ''Listening Session on Social Determinants of Health Data Elements: Summary of Findings,'' includes a list of participating stakeholders and their affiliations, and is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

(a) Race and Ethnicity

The persistence of racial and ethnic disparities in health and health care is widely documented, including in PAC settings.[771] [772] [773] [774] [775] Despite the trend toward overall improvements in quality of care and health outcomes, the Agency for Healthcare Research and Quality, in its National Healthcare Quality and Disparities Reports, consistently indicates that racial and ethnic disparities persist, even after controlling for factors such as income, geography, and insurance.[776] For example, racial and ethnic minorities tend to have higher rates of infant mortality, diabetes and other chronic conditions, and visits to the emergency department, and lower

[771] 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; September 2018. AHRQ Pub. No. 18–0033–EF.

[772] Fiscella, K. and Sanders, M.R. Racial and Ethnic Disparities in the Quality of Health Care. (2016). Annual Review of Public Health. 37:375–394.

[773] 2018 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Reports. Baltimore, MD: U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services; February 28, 2018.

[774] Smedley, B.D., Stith, A.Y., & Nelson, A.R. (2003). Unequal treatment: Confronting racial and ethnic disparities in health care. Washington, DC, National Academy Press.

[775] Chase, J., Huang, L. and Russell, D. (2017). Racial/ethnic disparities in disability outcomes among post-acute home care patients. *J of Aging and Health.* 30(9):1406–1426.

[776] National Healthcare Quality and Disparities Reports. (December 2018). Agency for Healthcare Research and Quality, Rockville, MD. *http://www.ahrq.gov/research/findings/nhqrdr/index.html.*

rates of having a usual source of care and receiving immunizations such as the flu vaccine.[777] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.[778] However, our ability to identify and address racial and ethnic health disparities has historically been constrained by data limitations, particularly for smaller populations groups such as Asians, American Indians and Alaska Natives, and Native Hawaiians and other Pacific Islanders.[779]

The ability to improve understanding of and address racial and ethnic disparities in PAC outcomes requires the availability of better data. There is currently a Race and Ethnicity data element, collected in the MDS, LCDS, IRF–PAI, and OASIS, that consists of a single question, which aligns with the 1997 Office of Management and Budget (OMB) minimum data standards for federal data collection efforts.[780] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. The 1997 OMB Standard also lists two minimum categories of ethnicity: (1) Hispanic or Latino; and (2) Not Hispanic or Latino. The 2011 HHS Data Standards requires a two-question format when self-identification is used to collect data on race and ethnicity. Large federal surveys such as the National Health Interview Survey, Behavioral Risk Factor Surveillance System, and the National Survey on Drug Use and Health, have implemented the 2011 HHS race and ethnicity data standards. CMS has similarly updated the Medicare Current Beneficiary Survey, Medicare Health Outcomes Survey, and the Health Insurance Marketplace Application for Health Coverage with the 2011 HHS data standards. More information about the HHS Race and Ethnicity Data Standards are available on the website at: *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54.*

We are proposing to revise the current Race and Ethnicity data element for purposes of this proposal to conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data standards for race and ethnicity. Rather than one data element that assesses both race and ethnicity, we are proposing two separate data elements: One for Race and one for Ethnicity, that would conform with the 2011 HHS Data Standards and the 1997 OMB Standard. In accordance with the 2011 HHS Data Standards, a two-question format would be used for the proposed race and ethnicity data elements.

The proposed Race data element asks, ''What is your race?'' We are proposing to include fourteen response options under the race data element: (1) White; (2) Black or African American; (3) American Indian or Alaska Native; (4) Asian Indian; (5) Chinese; (6) Filipino; (7) Japanese; (8) Korean; (9) Vietnamese; (10) Other Asian; (11) Native Hawaiian; (12) Guamanian or Chamorro; (13) Samoan; and, (14) Other Pacific Islander.

The proposed Ethnicity data element asks, ''Are you Hispanic, Latino/a, or Spanish origin?'' We are proposing to include five response options under the ethnicity data element: (1) Not of Hispanic, Latino/a, or Spanish origin; (2) Mexican, Mexican American, Chicano/a; (3) Puerto Rican; (4) Cuban; and, (5) Another Hispanic, Latino, or Spanish Origin.

We believe that the two proposed data elements for race and ethnicity conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data standards for race and ethnicity, because under those standards, more detailed information on population groups can be collected if those additional categories can be aggregated into the OMB minimum standard set of categories.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the importance of improving response options for race and ethnicity as a component of health care assessments and for monitoring disparities. Some stakeholders emphasized the importance of allowing for self-identification of race and ethnicity for more categories than are included in the 2011 HHS Standard to better reflect state and local diversity, while acknowledging the burden of coding an open-ended health care assessment question across different settings.

We believe that the proposed modified race and ethnicity data elements more accurately reflect the diversity of the U.S. population than the current race/ethnicity data element included in MDS, LCDS, IRF–PAI, and OASIS.[781] [782] [783] [784] We believe, and research consistently shows, that improving how race and ethnicity data are collected is an important first step in improving quality of care and health outcomes. Addressing disparities in access to care, quality of care, and health outcomes for Medicare beneficiaries begins with identifying and analyzing how SDOH, such as race and ethnicity, align with disparities in these areas.[785] Standardizing self-reported data collection for race and ethnicity allows for the equal comparison of data across multiple healthcare entities.[786] By collecting and analyzing these data, CMS and other healthcare entities will be able to identify challenges and monitor progress. The growing diversity of the U.S. population and knowledge of racial and ethnic disparities within and across population groups supports the collection of more granular data beyond the 1997 OMB minimum standard for reporting categories. The 2011 HHS race and ethnicity data standard includes additional detail that may be used by

[777] National Center for Health Statistics. Health, United States, 2017: With special feature on mortality. Hyattsville, Maryland. 2018.

[778] HHS. Heart disease and African Americans. 2016b. (October 24, 2016). *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[779] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK425844/.*

[780] ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Notice of Decision)''. **Federal Register** 62:210 (October 30, 1997) pp. 58782–58790. Available from: *https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf.*

[781] Penman-Aguilar, A., Talih, M., Huang, D., Moonesinghe, R., Bouye, K., Beckles, G. (2016). Measurement of Health Disparities, Health Inequities, and Social Determinants of Health to Support the Advancement of Health Equity. J Public Health Manag Pract. 22 Suppl 1: S33–42.

[782] Ramos, R., Davis, J.L., Ross, T., Grant, C.G., Green, B.L. (2012). Measuring health disparities and health inequities: do you have REGAL data? Qual Manag Health Care. 21(3):176–87.

[783] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[784] ''Revision of Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity: Proposals From Federal Interagency Working Group (Notice and Request for Comments).'' **Federal Register** 82: 39 (March 1, 2017) p. 12242.

[785] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK425844/.*

[786] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

PAC providers to target quality improvement efforts for racial and ethnic groups experiencing disparate outcomes. For more information on the Race and Ethnicity data elements, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Measures and Standardized Patient Assessment Data Elements,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of race and ethnicity data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Race and Ethnicity data elements described above as SPADEs with respect to the proposed Social Determinants of Health category.

Specifically, we are proposing to replace the current Race/Ethnicity data element with the proposed Race and Ethnicity data elements on the LCDS. We are also proposing that LTCHs that submit the Race and Ethnicity data elements with respect to admission will be considered to have submitted with respect to discharge as well, because it is unlikely that the results of these assessment findings will change between the start and end of the LTCH stay, making the information submitted with respect to a patient's admission the same with respect to a patient's discharge.

(b) Preferred Language and Interpreter Services

More than 64 million Americans speak a language other than English at home, and nearly 40 million of those individuals have limited English proficiency (LEP).[787] Individuals with LEP have been shown to receive worse care and have poorer health outcomes, including higher readmission rates.[788] [789] [790] Communication with individuals with LEP is an important component of high quality health care, which starts by understanding the population in need of language services. Unaddressed language barriers between a patient and provider care team negatively affects the ability to identify and address individual medical and non-medical care needs, to convey and understand clinical information, as well as discharge and follow up instructions, all of which are necessary for providing high quality care. Understanding the communication assistance needs of patients with LEP, including individuals who are Deaf or hard of hearing, is critical for ensuring good outcomes.

Presently, the preferred language of patients and need for interpreter services are assessed in two PAC assessment tools. The LCDS and the MDS use the same two data elements to assess preferred language and whether a patient or resident needs or wants an interpreter to communicate with health care staff. The MDS initially implemented preferred language and interpreter services data elements to assess the needs of SNF residents and patients and inform care planning. For alignment purposes, the LCDS later adopted the same data elements for LTCHs. The 2009 NASEM (formerly Institute of Medicine) report on standardizing data for health care quality improvement emphasizes that language and communication needs should be assessed as a standard part of health care delivery and quality improvement strategies.[791]

In developing our proposal for a standardized language data element across PAC settings, we considered the current preferred language and interpreter services data elements that are in LCDS and MDS. We also considered the 2011 HHS Primary Language Data Standard and peer-reviewed research. The current preferred language data element in LCDS and MDS asks, ''What is your preferred language?'' Because the preferred language data element is open-ended, the patient or resident is able to identify their preferred language, including American Sign Language (ASL). Finally, we considered the recommendations from the 2009 NASEM (formerly Institute of Medicine) report, ''Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement.'' In it, the committee recommended that organizations evaluating a patient's language and communication needs for health care purposes, should collect data on the preferred spoken language and on an individual's assessment of his/her level of English proficiency.

A second language data element in LCDS and MDS asks, ''Do you want or need an interpreter to communicate with a doctor or health care staff?'' and includes yes or no response options. In contrast, the 2011 HHS Primary Language Data Standard recommends either a single question to assess how well someone speaks English or, if more granular information is needed, a two-part question to assess whether a language other than English is spoken at home and if so, identify that language. However, neither option allows for a direct assessment of a patient's or resident's preferred spoken or written language nor whether they want or need interpreter services for communication with a doctor or care team, both of which are an important part of assessing patient and resident needs and the care planning process. More information about the HHS Data Standard for Primary Language is available on the website at: *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54.*

Research consistently recommends collecting information about an individual's preferred spoken language and evaluating those responses for purposes of determining language access needs in health care.[792] However, using ''preferred spoken language'' as the metric does not adequately account for people whose preferred language is ASL, which would necessitate adopting an additional data element to identify visual language. The need to improve the assessment of language preferences and communication needs across PAC settings should be balanced with the burden associated with data collection on the provider and patient. Therefore we are proposing to retain the Preferred Language and Interpreter Services data elements currently in use on the LCDS.

In addition, we received feedback during the December 13, 2018 listening session on the importance of evaluating and acting on language preferences early to facilitate communication and allowing for patient self-identification of preferred language. Although the discussion about language was focused on preferred spoken language, there was

[787] U.S. Census Bureau, 2013–2017 American Community Survey 5-Year Estimates.

[788] Karliner LS, Kim SE, Meltzer DO, Auerbach AD. Influence of language barriers on outcomes of hospital care for general medicine inpatients. *J Hosp Med.* 2010 May–Jun;5(5):276–82. doi: 10.1002/jhm.658.

[789] Kim EJ, Kim T, Paasche-Orlow MK, et al. Disparities in Hypertension Associated with Limited English Proficiency. *J Gen Intern Med.* 2017 Jun;32(6):632–639. doi: 10.1007/s11606–017–3999–9.

[790] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

[791] IOM (Institute of Medicine). 2009. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement.* Washington, DC: The National Academies Press.

[792] Guerino, P. and James, C. Race, Ethnicity, and Language Preference in the Health Insurance Marketplaces 2017 Open Enrollment Period. Centers for Medicare & Medicaid Services, Office of Minority Health. Data Highlight: Volume 7—April 2017. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-Race-Ethnicity-and-Language-Preference-Marketplace.pdf.*

general consensus among participants that stated language preferences may or may not accurately indicate the need for interpreter services, which supports collecting and evaluating data to determine language preference, as well as the need for interpreter services. An alternate suggestion was made to inquire about preferred language specifically for discussing health or health care needs. While this suggestion does allow for ASL as a response option, we do not have data indicating how useful this question might be for assessing the desired information and thus we are not including this question in our proposal.

Improving how preferred language and need for interpreter services data are collected is an important component of improving quality by helping PAC providers and other providers understand patient needs and develop plans to address them. For more information on the Preferred Language and Interpreter Services data elements, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of language data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Preferred Language and Interpreter Services data elements currently used on the LCDS, and describe above, as SPADEs with respect to the Social Determinants of Health category.

(c) Health Literacy

The Department of Health and Human Services defines health literacy as ''the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.'' [793] Similar to language barriers, low health literacy can interfere with communication between the provider and patient and the ability for patients or their caregivers to understand and follow treatment plans, including medication management. Poor health literacy is linked to lower levels of knowledge about health, worse health outcomes, and the receipt of fewer preventive services, but higher medical costs and rates of emergency department use.[794]

Health literacy is prioritized by Healthy People 2020 as an SDOH.[795] Healthy People 2020 is a long-term, evidence-based effort led by the Department of Health and Human Services that aims to identify nationwide health improvement priorities and improve the health of all Americans. Although not designated as a social risk factor in NASEM's 2016 report on accounting for social risk factors in Medicare payment, the NASEM noted that health literacy is impacted by other social risk factors and can affect access to care as well as quality of care and health outcomes.[796] Assessing for health literacy across PAC settings would facilitate better care coordination and discharge planning. A significant challenge in assessing the health literacy of individuals is avoiding excessive burden on patients and health care providers. The majority of existing, validated health literacy assessment tools use multiple screening items, generally with no fewer than four, which would make them burdensome if adopted in MDS, LCDS, IRF–PAI, and OASIS.

The Single Item Literacy Screener (SILS) question asks, ''How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?'' Possible response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always. The SILS question, which assesses reading ability, (a primary component of health literacy), tested reasonably well against the 36 item Short Test of Functional Health Literacy in Adults (S–TOFHLA), a thoroughly vetted and widely adopted health literacy test, in assessing the likelihood of low health literacy in an adult sample from primary care practices participating in the Vermont Diabetes Information System.[797] [798] The S–TOFHLA is a more complex assessment instrument developed using actual hospital related materials such as prescription bottle labels and appointment slips, and often considered the instrument of choice for a detailed evaluation of health literacy.[799] Furthermore, the S–TOFHLA instrument is proprietary and subject to purchase for individual entities or users.[800] Given that SILS is publicly available, shorter and easier to administer than the full health literacy screen, and research found that a positive result on the SILS demonstrates an increased likelihood that an individual has low health literacy, we are proposing to use the single-item reading question for health literacy in the standardized data collection across PAC settings. We believe that use of this data element will provide sufficient information about the health literacy of LTCH patients to facilitate appropriate care planning, care coordination, and interoperable data exchange across PAC settings.

In addition, we received feedback during the December 13, 2018 SDOH listening session on the importance of recognizing health literacy as more than understanding written materials and filling out forms, as it is also important to evaluate whether patients understand their conditions. However, the NASEM recently recommended that health care providers implement health literacy universal precautions instead of taking steps to ensure care is provided at an appropriate literacy level based on individualized assessment of health literacy.[801] Given the dearth of Medicare data on health literacy and gaps in addressing health literacy in practice,

[793] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National action plan to improve health literacy. Washington (DC): Author; 2010.

[794] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

[795] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.* (February 2019).

[796] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.* Washington, DC: 2016.

[797] Morris, N.S., MacLean, C.D., Chew, L.D., & Littenberg, B. (2006). The Single Item Literacy Screener: Evaluation of a brief instrument to identify limited reading ability. BMC family practice, 7, 21. doi:10.1186/1471–2296–7–21.

[798] Brice, J.H., Foster, M.B., Principe, S., Moss, C., Shofer, F.S., Falk, R.J., Ferris, M.E., DeWalt, D.A. (2013). Single-item or two-item literacy screener to predict the S–TOFHLA among adult hemodialysis patients. Patient Educ Couns. 94(1):71–5.

[799] University of Miami, School of Nursing & Health Studies, Center of Excellence for Health Disparities Research. Test of Functional Health Literacy in Adults (TOFHLA). (March 2019). Available from: *https://elcentro.sonhs.miami.edu/research/measures-library/tofhla/index.html.*

[800] Nurss, J.R., Parker, R.M., Williams, M.V., &Baker, D.W. David W. (2001). TOFHLA. Peppercorn Books & Press. Available from: *http://www.peppercornbooks.com/catalog/information.php?info_id=5.*

[801] Hudson, S., Rikard, R.V., Staiculescu, I. & Edison, K. (2017). Improving health and the bottom line: The case for health literacy. In Building the case for health literacy: Proceedings of a workshop. Washington, DC: The National Academies Press.

we recommend the addition of a health literacy data element.

The proposed Health Literacy data element is consistent with considerations raised by NASEM and other stakeholders and research on health literacy, which demonstrates an impact on health care use, cost, and outcomes.[802] For more information on the proposed Health Literacy data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of health literacy data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the SILS question, described above for the Health Literacy data element, as SPADE under the Social Determinants of Health category. We are proposing to add the Health Literacy data element to the LCDS.

(d) Transportation

Transportation barriers commonly affect access to necessary health care, causing missed appointments, delayed care, and unfilled prescriptions, all of which can have a negative impact on health outcomes.[803] Access to transportation for ongoing health care and medication access needs, particularly for those with chronic diseases, is essential to successful chronic disease management. Adopting a data element to collect and analyze information regarding transportation needs across PAC settings would facilitate the connection to programs that can address identified needs. We are therefore proposing to adopt as SPADE a single transportation data element that is from the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) assessment tool and currently part of the Accountable Health Communities (AHC) Screening Tool.

The proposed Transportation data element from the PRAPARE tool asks, ''Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living?'' The three response options are: (1) Yes, it has kept me from medical appointments or from getting my medications; (2) Yes, it has kept me from non-medical meetings, appointments, work, or from getting things that I need; and (3) No. The patient would be given the option to select all responses that apply. We are proposing to use the transportation data element from the PRAPARE Tool, with permission from National Association of Community Health Centers (NACHC), after considering research on the importance of addressing transportation needs as a critical SDOH.[804]

The proposed data element is responsive to research on the importance of addressing transportation needs as a critical SDOH and would adopt the Transportation item from the PRAPARE tool.[805] This data element comes from the national PRAPARE social determinants of health assessment protocol, developed and owned by NACHC, in partnership with the Association of Asian Pacific Community Health Organization, the Oregon Primary Care Association, and the Institute for Alternative Futures. Similarly the Transportation data element used in the AHC Screening Tool was adapted from the PRAPARE tool. The AHC screening tool was implemented by the Center for Medicare and Medicaid Innovation's AHC Model and developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including transportation. While the transportation access data element in the AHC screening tool serves the same purposes as our proposed SPADE collection about transportation barriers, the AHC tool has binary yes or no response options that do not differentiate between challenges for medical versus non-medical appointments and activities. We believe that this is an important nuance for informing PAC discharge planning to a community setting, as transportation needs for non-medical activities may differ than for medical activities and should be taken into account.[806] We believe that use of this data element will provide sufficient information about transportation barriers to medical and non-medical care for LTCH patients to facilitate appropriate discharge planning and care coordination across PAC settings. As such, we are proposing to adopt the Transportation data element from PRAPARE. More information about development of the PRAPARE tool is available on the website at: *https://protect2.fireeye.com/url?k=7cb6eb44-20e2f238-7cb6da7b-0cc47adc5fa2-1751cb986c8c2f8c&u=http://www.nachc.org/prapare*.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the impact of transportation barriers on unmet care needs. While recognizing that there is no consensus in the field about whether providers should have responsibility for resolving patient transportation needs, discussion focused on the importance of assessing transportation barriers to facilitate connections with available community resources.

Adding a Transportation data element to the collection of SPADE would be an important step to identifying and addressing SDOH that impact health outcomes and patient experience for Medicare beneficiaries. For more information on the Transportation data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of transportation data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Transportation data element described above as SPADE with respect to the proposed Social Determinants of Health category. If finalized as proposed, we would add the Transportation data element to the LCDS.

(e) Social Isolation

Distinct from loneliness, social isolation refers to an actual or perceived lack of contact with other people, such as living alone or residing in a remote

[802] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press.

[803] Syed, S.T., Gerber, B.S., and Sharp, L.K. (2013). Traveling Towards Disease: Transportation Barriers to Health Care Access. *J Community Health*. 38(5): 976–993.

[804] Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at: *www.aha.org/transportation.www.aha.org/transportation.*

[805] Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at: *www.aha.org/transportation.*

[806] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

area.[807] [808] Social isolation tends to increase with age, is a risk factor for physical and mental illness, and a predictor of mortality.[809] [810] [811] Post-acute care providers are well-suited to design and implement programs to increase social engagement of patients, while also taking into account individual needs and preferences. Adopting a data element to collect and analyze information about social isolation in LTCHs and across PAC settings would facilitate the identification of patients who are socially isolated and who may benefit from engagement efforts.

We are proposing to adopt as SPADE a single social isolation data element that is currently part of the AHC Screening Tool. The AHC item was selected from the Patient-Reported Outcomes Measurement Information System (PROMIS®) Item Bank on Emotional Distress and asks, ''How often do you feel lonely or isolated from those around you?'' The five response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always.[812] The AHC Screening Tool was developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including social isolation. More information about the AHC Screening Tool is available on the website at: *https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf.*

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the value of receiving information on social isolation for purposes of care planning. Some stakeholders also recommended assessing social isolation as an SDOH as opposed to social support.

The proposed Social Isolation data element is consistent with NASEM considerations about social isolation as a function of social relationships that impacts health outcomes and increases mortality risk, as well as the current work of a NASEM committee examining how social isolation and loneliness impact health outcomes in adults 50 years and older. We believe that adding a Social Isolation data element would be an important component of better understanding patient complexity and the care goals of patients, thereby facilitating care coordination and continuity in care planning across PAC settings. For more information on the Social Isolation data element, we refer readers to the document titled ''Proposed Specifications for LTCH QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of social isolation data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Social Isolation data element described above as SPADE with respect to the proposed Social Determinants of Health category. We are proposing to add the Social Isolation data element to the LCDS.

We are soliciting comment on these proposals.

8. Proposed Form, Manner, and Timing of Data Submission Under the LTCH QRP

a. Background

We refer readers to the regulations at § 412.560(b) for information regarding the current policies for reporting LTCH QRP data.

b. Update to the CMS System for Reporting Quality Measures and Standardized Patient Assessment Data and Associated Procedural Proposals

LTCHs are currently required to submit LCDS data to CMS using the Quality Improvement and Evaluation System (QIES) Assessment and Submission Processing (ASAP) system. We have recently migrated to a new internet Quality Improvement and Evaluation System (iQIES) that will enable real-time upgrades, and we are proposing to designate that system as the data submission system for the LTCH QRP beginning October 1, 2019. We are also proposing to revise our regulations at § 412.560(d)(1) by replacing the reference to ''Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system'' with ''CMS designated data submission system'', and to revise § 412.560(d)(3) and § 412.560(f)(1) by replacing the references to ''QIES ASAP system'' with ''CMS designated data submission system'' effective October 1, 2019. In addition, we are proposing to notify the public of any future changes to the CMS designated system using subregulatory mechanisms such as website postings, listserv messaging, and webinars.

c. Proposed Reporting Requirement Updates Beginning With the FY 2022 LTCH QRP

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20515), we sought public comment on moving the implementation date of any new version of the LCDS from April to October of the same year. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41633), we summarized the comments we received on this topic. After considering those comments, and to align with the MDS and IRF–PAI implementation dates, in this proposed rule, we are proposing to move the implementation date of any new version of the LCDS from April to October, beginning October 1, 2020. This would provide LTCHs an additional 6 months to prepare for any changes to the reporting requirements.

We are also proposing that, for the first program year in which measures or standardized patient assessment data are adopted, LTCHs would only be required to report data on patients who are admitted and discharged during the last quarter (October 1 to December 31) of the calendar year that applies to the program year. For subsequent program years, LTCHs would be required to report data on patients who are admitted and discharged during the 12-month calendar year that applies to the program year.

The tables below illustrate the proposed quarterly data collection reporting periods and data submission deadlines using the FY 2022 LTCH QRP and FY 2023 LTCH QRP. The data submission deadline applies to all measures and standardized patient assessment data except the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

[807] Tomaka, J., Thompson, S., and Palacios, R. (2006). The Relation of Social Isolation, Loneliness, and Social Support to Disease Outcomes Among the Elderly. J of Aging and Health. 18(3): 359–384.

[808] Social Connectedness and Engagement Technology for Long-Term and Post-Acute Care: A Primer and Provider Selection Guide. (2019). Leading Age. Available at: *https://www.leadingage.org/white-papers/social-connectedness-and-engagement-technology-long-term-and-post-acute-care-primer-and#1.1.*

[809] Landeiro, F., Barrows, P., Nuttall Musson, E., Gray, A.M., and Leal, J. (2017). Reducing Social Loneliness in Older People: A Systematic Review Protocol. BMJ Open. 7(5): e013778.

[810] Ong, A.D., Uchino, B.N., and Wethington, E. (2016). Loneliness and Health in Older Adults: A Mini-Review and Synthesis. *Gerontology.* 62:443–449.

[811] Leigh-Hunt, N., Bagguley, D., Bash, K., Turner, V., Turnbull, S., Valtorta, N., and Caan, W. (2017). An overview of systematic reviews on the public health consequences of social isolation and loneliness. *Public Health.* 152:157–171.

[812] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

measure data, which is submitted annually.

INITIAL REPORTING PERIOD FOR QUALITY MEASURES * AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING FOR THE FY 2022 LTCH QRP **

Proposed data collection quarterly reporting period	Proposed data submission quarterly deadlines beginning with the FY 2022 LTCH QRP
CY 2020 Q4: 10/1/2020–12/31/2020	CY 2020 Q4 Deadline: May 15, 2021.

* The submission deadline for the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) is annual, not quarterly. The proposed data collection reporting period for the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) for the FY 2022 LTCH QRP is 10/1/2020–3/31/2021 and its proposed deadline is May 15, 2021.
** Applies to data reporting using the LCDS and CDC's NHSN.

CALENDAR YEAR REPORTING PERIOD FOR QUALITY MEASURES * AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING FOR THE FY 2023 LTCH QRP **

Proposed data collection quarterly reporting period	Proposed data submission quarterly deadlines beginning with the FY 2023 LTCH QRP
CY 2021 Q1: 1/1/2021–3/31/2021	CY 2021 Q1 Deadline: August 15, 2021.
CY 2021 Q2: 4/1/2021–6/30/2021	CY 2021 Q2 Deadline: November 15, 2021.
CY 2021 Q3: 7/1/2021–9/30/2021	CY 2021 Q3 Deadline: February 15, 2022.
CY 2021 Q4: 10/1/2021–12/31/2021	CY 2021 Q4 Deadline: May 15, 2022.

* The submission deadline for the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) is annual, not quarterly. The proposed data collection reporting period for the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) for the FY 2023 LTCH QRP is 10/1/2021–3/31/2022 and its proposed deadline is May 15, 2022.
** Applies to data reporting using the LCDS and CDC's NHSN.

d. Proposed Schedule for Reporting the Transfer of Health Information Quality Measures Beginning With the FY 2022 LTCH QRP

As discussed in section VIII.C.4. of the preamble of this proposed rule, we are proposing to adopt the Transfer of Health Information to the Provider—Post-Acute Care (PAC) and Transfer of Health Information to the Patient—Post-Acute Care (PAC) quality measures beginning with the FY 2022 LTCH QRP. We also are proposing that LTCHs would report the data on those measures using the LCDS. LTCHs would be required to collect data on both measures for all patients beginning with October 1, 2020 discharges. We refer readers to the tables in section VIII.C.8.c. of the preamble of this proposed rule for an illustration of the initial and calendar year reporting cycles.

e. Proposed Schedule for Reporting Standardized Patient Assessment Data Elements Beginning With the FY 2022 LTCH QRP

As discussed in section VIII.C.7. of the preamble of this proposed rule, we are proposing to adopt SPADEs beginning with the FY 2022 LTCH QRP. We are proposing that LTCHs would report the data using the LCDS. Similar to the proposed schedule for reporting the Transfer of Health Information to the Provider—Post-Acute Care (PAC) and Transfer of Health Information to the Patient—Post-Acute Care (PAC) quality measures, LTCHs would be required to collect the SPADEs for all patients beginning with October 1, 2020 admissions and discharges. LTCHs that submit data with respect to admission for the Hearing, Vision, Race, and Ethnicity SPADEs would be considered to have submitted data with respect to discharge. We refer readers to the tables in section VIII.C.8.c. of the preamble of this proposed rule for an illustration of the initial and calendar year reporting cycles.

9. Proposed Removal of the List of Compliant LTCHs

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49754 through 49755), we finalized that we would publish a list of LTCHs that successfully met the reporting requirements for the applicable payment determination on the LTCH QRP website and update the list on an annual basis.

We have received feedback from stakeholders that this list offers minimal benefit. Although the posting of successful providers was the final step in the applicable payment determination process, it does not provide new information or clarification to the providers regarding their annual payment update status. Therefore, in this proposed rule, we are proposing that we will no longer publish a list of compliant LTCHs on the LTCH QRP website effective beginning with the FY 2020 payment determination.

10. Proposed Policies Regarding Public Display of Measure Data for the LTCH QRP

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making the LTCH QRP data available to the public after ensuring that LTCHs have the opportunity to review their data prior to public display. Measure data are currently displayed on the *LTCH Compare* website, an interactive web tool that assists individuals by providing information on LTCH quality of care. For more information on *LTCH Compare,* we refer readers to our website at: *https://www.medicare.gov/longtermcarehospitalcompare/.* For a more detailed discussion about our policies regarding public display of LTCH QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57231 through 57236). In this proposed rule, we are proposing to begin publicly displaying data for the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) measure beginning CY 2020 or as soon as technically feasible. We finalized the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) measure in the FY 2017

IPPS/LTCH PPS final rule (81 FR 57219 through 57223).

Data collection for this assessment-based measure began with patients admitted and discharged on or after July 1, 2018. We are proposing to display data based on four rolling quarters, initially using discharges from January 1, 2019 through December 31, 2019 (Quarter 1 2019 through Quarter 4 2019). To ensure the statistical reliability of the data, we are proposing that we would not publicly report an LTCH's performance on the measure if the LTCH had fewer than 20 eligible cases in any four consecutive rolling quarters. LTCHs that have fewer than 20 eligible cases would be distinguished with a footnote that states: ''The number of cases/patient stays is too small to publicly report.''

D. Proposed Changes to the Medicare and Medicaid Promoting Interoperability Programs

1. Background

a. Statutory Authority for the Medicare and Medicaid Promoting Interoperability Programs

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record technology (CEHRT). Incentive payments under Medicare were available to eligible hospitals and CAHs for certain payment years (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrated meaningful use of CEHRT, which included reporting on clinical quality measures (CQMs) using CEHRT. Incentive payments were available to Medicare Advantage (MA) organizations under section 1853(m)(3) of the Act for certain affiliated hospitals that meaningfully used CEHRT. In accordance with the timeframe set forth in the statute, these incentive payments under Medicare generally are no longer available, except for Puerto Rico eligible hospitals (for more information on the Medicare incentive payments available to Puerto Rico eligible hospitals, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41672 through 41675).

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act also establish downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of CEHRT for certain associated reporting periods. Section 1853(m)(4) of the Act establishes a negative payment adjustment to the monthly prospective payments of a qualifying MA organization if its affiliated eligible hospitals are not meaningful users of CEHRT, beginning in 2015.

Section 1903(a)(3)(F)(i) of the Act establishes 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade and meaningfully use CEHRT.

b. Goals of Proposed Changes to the Medicare and Medicaid Promoting Interoperability Programs

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41635), we affirmed our commitment to furthering interoperability by changing the name of the EHR Incentive Program to the Promoting Interoperability Program. As we look toward the future of the Promoting Interoperability Program, the general goals of our proposals in this proposed rule include: (1) A priority of stability within the program after the recent changes made in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41634 through 41677) while continuing to further interoperability through the use of CEHRT; (2) reducing administrative burden; (3) continued use of the 2015 Edition CEHRT; and (4) improving patient access to their EHRs so they can make fully informed health care decisions.

2. EHR Reporting Period

a. Proposed Change to the EHR Reporting Period in CY 2019 for Eligible Hospitals

Under § 495.4, in the definition of ''EHR reporting period for a payment adjustment year,'' for 2019, if an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2019 and applies for the FY 2020 and 2021 payment adjustment years. For the FY 2020 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2019.

We are proposing that, if we finalize our proposal to modify the Query of PDMP measure to require a ''yes/no'' attestation response instead of a numerator/denominator, as discussed in greater detail in section VIII.D.3.b. of the preamble of this proposed rule, we would eliminate the October 1, 2019 deadline for an eligible hospital that has not successfully demonstrated it is a meaningful EHR user in a prior year. This proposal would provide such eligible hospitals all of CY 2019 to complete their respective 90-day EHR reporting period for the FY 2020 payment adjustment year. We are proposing to revise the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4 to reflect this proposal.

b. Proposed EHR Reporting Period in CY 2021

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636), and codified in the definitions of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4, the EHR reporting period in CY 2020 is a minimum of any continuous 90-day period in CY 2020 for new and returning participants in the Promoting Interoperability Programs attesting to CMS or their State Medicaid agency. Eligible professionals, eligible hospitals, and CAHs may select an EHR reporting period of a minimum of any continuous 90-day period in CY 2020 from January 1, 2020 through December 31, 2020.

For CY 2021, we are proposing an EHR reporting period of a minimum of any continuous 90-day period in CY 2021 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program attesting to CMS. We believe that this is an appropriate length of time for the EHR reporting period because of the updates to measures and other changes being proposed in this proposed rule. In addition, a minimum of any continuous 90-day period in CY 2021 would offer stability to the Promoting Interoperability Program after the changes that were finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41634 through 41677). We are proposing corresponding changes to the definitions of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4.

In the July 28, 2010 final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program'' at 75 FR 44319, we established that, in accordance with section 1903(t)(5)(D) of the Act, in no case may any Medicaid eligible hospital receive an incentive after 2021 (see 42 CFR 495.310(f)). Therefore, December 31, 2021 is the last date that States could make Medicaid Promoting Interoperability Program payments to Medicaid eligible hospitals (other than pursuant to a successful appeal related to 2021 or a prior year). For additional discussion of this issue, we refer readers

to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41676 through 41677) and the CY 2019 PFS/QPP final rule (83 FR 59704 through 59706). As discussed in those rules, the same deadline applies to Medicaid Promoting Interoperability Program incentive payments to Medicaid eligible professionals, under section 1903(t)(4)(A)(iii) of the Act and 42 CFR 495.310(a)(2)(v). To help States meet this deadline, in the CY 2019 PFS/QPP final rule (83 FR 59704 through 59706), we changed the CY 2021 EHR and CQM reporting periods for Medicaid eligible professionals. However, we did not change the 2021 EHR and CQM reporting periods for Medicaid eligible hospitals in that rule, and are not proposing to do so in this proposed rule.

That is because, based on attestation data and information from State Medicaid Health Information Technology Plans regarding the number of years States disburse Medicaid Promoting Interoperability Program payments to hospitals, we believe that there will be no hospitals eligible to receive Medicaid Promoting Interoperability Program payments in 2021 due to the requirement that, after 2016, eligible hospitals cannot receive a Medicaid Promoting Interoperability Program payment unless they have received such a payment for the prior fiscal year. At this time, we believe that there are no Medicaid-only eligible hospitals or ''dually-eligible'' hospitals (those that are eligible for an incentive payment under Medicare for meaningful use of CEHRT and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use of CEHRT, and are also eligible to earn a Medicaid incentive payment for meaningful use of CEHRT) that will be able to receive Medicaid Promoting Interoperability Program payments in 2021. We invited comments on whether this belief was accurate in the CY 2019 PFS/QPP rulemaking (83 FR 35873) and received one comment agreeing with us, but we also stated that we would solicit additional comments on this issue in a proposed rule that is more specifically related to hospital payment (83 FR 59705 through 59706). Accordingly, we are again inviting comments on whether we are correct in thinking that there are no hospitals that would be able to receive Medicaid Promoting Interoperability Program payments in 2021. If this is not true, we are seeking comment on how we should adjust 2021 reporting periods for Medicaid eligible hospitals in a manner that limits the burden on hospitals and States.

b. Promoting Interoperability Measures: Actions Must Occur Within the EHR Reporting Period

Stakeholders have questioned whether the actions in the numerator for the Medicare Promoting Interoperability Program are limited to the EHR reporting period or if we allow the numerator to continue to increment outside of the EHR reporting period but within the calendar year. We note that we had issued a frequently asked question (FAQ number 8231 [813]) applicable to the Medicare and Medicare EHR Incentive Programs. The FAQ stated that, regarding the reporting of numerators, ''the . . . numerator is not constrained to the EHR reporting period unless expressly stated in the numerator statement.'' The FAQ went further to state that, for some measures, ''the actions may reasonably fall outside of the EHR reporting period time frame but must take place no earlier than the start of the reporting year and no later than the date of attestation, in order for patients to be counted in the numerator.'' When we adopted a new scoring methodology and revised objectives and measures for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program last year in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41634 through 41677), we neglected to state whether the policy in the FAQ would still be applicable in light of the changes to the objectives and measures. As we have established an EHR reporting period that is a minimum of 90 consecutive days, eligible hospitals and CAHs may select an EHR reporting period that ranges from 90 days to the entire CY so that the numerators would increment over a longer period of time. Therefore, we are proposing that, beginning with the EHR reporting period in CY 2020, for eligible hospitals and CAHs that submit an attestation to CMS under the Medicare Promoting Interoperability Program, both the numerators and denominators of measures in the Medicare Promoting Interoperability Program would only increment based on actions that have occurred during the EHR reporting period that was selected by the eligible hospital or CAH. We are proposing to codify this proposed policy at § 495.24(e)(1)(ii).

However, there is one exception to this proposed policy, and that is the Security Risk Analysis measure. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41644), we finalized that the actions included in the Security Risk Analysis measure may occur any time during the calendar year in which the EHR reporting period occurs. We are proposing to revise § 495.24(e)(4)(iii) to reflect this existing policy for the Security Risk Analysis measure.

While this proposed policy is reflected in certain denominators and measure descriptions in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41659 through 41660), we did not apply this policy to all of the measures. As mentioned above, our intent is to have this policy apply to all measures of the Medicare Promoting Interoperability Program, with the Security Risk Analysis measure being the only exception. Currently, the following measures limit the actions to the EHR reporting period: E-Prescribing; Query of PDMP; Verify Opioid Treatment Agreement; Support Electronic Referral Loops by Sending Health Information; Provide Patients Electronic Access to Their Health Information; and Support Electronic Referral Loops by Receiving and Incorporating Health Information. The measures associated with the Public Health and Clinical Data Exchange Objective do not contain this limitation.

However, these proposals would not apply to the Medicaid Promoting Interoperability Program. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41658 through 41665), we removed several measures from the Medicare Promoting Interoperability Program that remained in the Medicaid Promoting Interoperability Program for eligible hospitals. Among those are measures that we believe it would be appropriate to continue our current policy of allowing eligible hospitals to count actions in the numerator that were taken outside the EHR reporting period, but within the calendar year in which the EHR reporting period occurs and no later than the date of attestation. For example, Objective 6: Coordination of Care through Patient Engagement, Measure 1 (view, download, or transmit) and Measure 2 (secure messaging) allow hospitals to count actions taken outside of the EHR reporting period in the numerator. We believe that the patient engagement that this objective promotes is important throughout the entire year and not just during the hospital's chosen EHR reporting period. We believe it is a more appropriate policy to continue to allow eligible hospitals to report actions in the numerators of these measures that are taken outside of the EHR reporting period, but within the calendar year in which the EHR reporting period occurs and no later than the date of attestation. Therefore, we are not proposing to change to the Medicaid Promoting Interoperability

[813] *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/FAQs.pdf.*

Program policy for either eligible hospitals or eligible professionals. Unless the numerator of a measure is specifically restricted to the EHR reporting period in the measure specifications, we will continue to allow health care providers to include actions taken before, during, or after the EHR reporting period if the period is less than one full year; however, these actions must be taken no earlier than the start of the same year as the EHR reporting period and no later than the date of attestation.

We do not believe this variation in policies would place burden on any health care providers. While our current policy gives discretion to health care providers who attest to a State Medicaid agency to include actions taken outside of the EHR reporting period, it does not require them to do so. Eligible hospitals that attest to a State Medicaid agency may choose to follow the policy proposed in this proposed rule for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program and only include actions taken within the EHR reporting period. Similarly, eligible professionals that attest to a State Medicaid agency may choose to follow the policy adopted for the MIPS Promoting Interoperability performance category.

3. Proposed Changes to Measures Under the Electronic Prescribing Objective

a. Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41648 through 41656), we adopted two opioid measures as for the Electronic Prescribing objective: (1) Query of Prescription Drug Monitoring Program (PDMP), which is optional in CY 2019 and required beginning in CY 2020; and (2) Verify Opioid Treatment Agreement, which is optional in CY 2019 and 2020. In addition, we stated that we intended to propose in rulemaking this year that EHR–PDMP integration would be required beginning in CY 2020 as part of the Query of PDMP measure (83 FR 41652). We believe incorporating a requirement for integration between PDMPs and the CEHRT utilized by eligible hospitals and CAHs would advance access to and usability of PDMP data by health care providers and reduce health care provider burden associated with the actions of this measure. Integration could reflect a variety of different approaches for interaction between EHRs and PDMPs that are currently being pursued in different locations and settings.

We received extensive comments on the Query of PDMP measure and our intent to require EHR–PDMP integration, as well as on the Verify Opioid Treatment Agreement measure, from stakeholders both during the comment period for the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 41648 through 41656), and subsequently through public forums and correspondence. While this feedback is the main catalyst for our proposals, below, there have also been significant legislative changes that have the potential to positively impact the Promoting Interoperability Program, specifically the Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) (Pub. L. 115–271). This legislation was enacted to address the opioid crisis and affects a wide range of HHS programs and policies. While this legislation is not the main reason for our proposals, we believe it may significantly affect the maturation, requirements, and use of PDMPs and State networks upon which the Query of PDMP measure is dependent.

In this proposed rule, we are aiming to be responsive to the comments that we have received from stakeholders since the FY 2019 IPPS/LTCH PPS final rule was published and to take into account certain aspects of the SUPPORT for Patients and Communities Act that may have implications for the policy goals of the Promoting Interoperability Program.

As explained in further detail below, we are proposing to make certain changes to the Query of PDMP and Verify Opioid Treatment Agreement measures. In section VIII.D.6.b. of the preamble of this proposed rule, we are proposing to adopt two opioid clinical quality measures beginning with the reporting period in CY 2021. In section VIII.D.7.a. and b. of the preamble of this proposed rule, we are also requesting information on potential new opioid use disorder (OUD) prevention and treatment-related measures. We believe the request for information will help to inform future rulemaking and not only help prevent and treat substance use disorder, but allow us to adopt measures that enable flexibility without added burden for health care providers. We value stakeholders' continued interest in and support for combating the nation's opioid epidemic.

b. Query of PDMP Measure

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41637 through 41645), we finalized that the Query of PDMP measure is optional and available for bonus points for CY 2019, and required in CY 2020. We stated that we would be moving towards requiring EHR–PDMP integration in CY 2020 (83 FR 41652). We gave eligible hospitals and CAHs flexibility in implementing this measure, including the flexibility to query the PDMP in any manner allowed under their State law (83 FR 41649).

However, we have received substantial feedback from health IT vendors and hospitals that this flexibility presents unintended challenges, such as the significant burden associated with IT system design and development needed to accommodate the measure and any future changes to it. During the FY 2019 IPPS/LTCH PPS proposed rule comment period (83 FR 41649 through 41653) and after the final rule was published, these stakeholders stated that it is premature to require the Query of PDMP measure in CY 2020 especially given the maturation needed in PDMP development.

We agree with stakeholders that PDMPs are still maturing in their development and use. As stated by the Substance Abuse and Mental Health Services Administration (SAMHSA), ''PDMPs operate independently within states and are not currently linked into a larger system; therefore, no comprehensive national PDMP prescription data are available. Moreover, there is no uniform way of accessing PDMP data across states, as data platforms differ by state.'' [814]

Stakeholders also mentioned the challenge posed by the current lack of integration of PDMPs into the EHR workflow. Historically, health care providers have had to go outside of the EHR workflow in order to separately log in to and access the State PDMP. In addition, stakeholders noted the wide variation in whether PDMP data can be stored in the EHR. By integrating PDMP data into the health record, health care providers can improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions. ONC is currently engaged in an assessment to better understand the current state of policy and technical factors impacting PDMP integration across States. This assessment is exploring factors like PDMP data integration, standards and hubs used to facilitate interstate PMDP data exchange, access permissions, and laws

[814] *https://www.samhsa.gov/capt/sites/default/files/resources/pdmp-overview.pdf.*

and regulations governing PDMP data storage.

In October 2018, the SUPPORT for Patients and Communities Act became law, signifying an important investment and approach for our nation in combating the opioid epidemic. The provisions of this law aim to provide for opioid use disorder prevention, recovery, and treatment and aim to increase access to evidence-based treatment and follow-up care included through legislative changes specific to the Medicare and Medicaid programs. Specifically, with respect to PDMPs, the SUPPORT for Patients and Communities Act includes new requirements and federal funding for PDMP enhancement, integration, and interoperability, and establishes mandatory use of PDMPs by certain Medicaid providers, in an effort to help reduce opioid misuse and overprescribing, and in an effort to help promote the overall effective prevention and treatment of opioid use disorder.

Section 5042(a) of the SUPPORT for Patients and Communities Act added section 1944 to the Act, titled ''Requirements relating to qualified prescription drug monitoring programs and prescribing certain controlled substances.'' This section increases federal Medicaid matching rates during FY 2019 and 2020 for certain State expenditures relating to qualified PDMPs administered by States. Under section 1944(b)(1) of the Act, to be a qualified PDMP, a PDMP must facilitate access by a covered provider to, at a minimum, the following information with respect to a covered individual, in as close to real-time as possible: Information regarding the prescription drug history of a covered individual with respect to controlled substances; the number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period; and the name, location, and contact information of each covered provider who prescribed a controlled substance to the covered individual during at the least the most recent 12-month period. Under section 1944(b)(2) of the Act, a qualified PDMP must also facilitate the integration of the information described in section 1944(b)(1) of the Act into the workflow of a covered provider, which may include the electronic system used by the covered provider for prescribing controlled substances.

Section 1944(f) of the Act establishes, for FY 2019 and FY 2020, a 100 percent Federal Medicaid matching rate for state expenditures to design, develop, or implement a PDMP that meets the requirements outlined in section 1944(b)(1) and (2) of the Act, and to make connections to that PDMP. Section 1944(f)(2) of the Act specifies that, to qualify for the 100 percent Federal matching rate, a State must have in place agreements with all contiguous States that, when combined, enable covered providers in all the contiguous States to access, through the PDMP, all information described in 1944(b)(1) of the Act. Section 5042(b) of the SUPPORT for Patients and Communities Act requires CMS, in consultation with the Centers for Disease Control and Prevention (CDC), to issue guidance not later than October 1, 2019 on best practices on the uses of PDMPs required of prescribers and on protecting the privacy of Medicaid beneficiary information maintained in and accessed through PDMPs. Further, section 5042(c) of the SUPPORT for Patients and Communities Act requires that HHS develop and publish, not later than October 1, 2020, model practices to assist State Medicaid program operations in identifying and implementing strategies to utilize data-sharing agreements described in section 1944(b) of the Act for the following purposes: Monitoring and preventing fraud, waste, and abuse; and improving health care for individuals enrolled in Medicaid who transition in and out of Medicaid coverage, who may have sources of health care coverage in addition to Medicaid coverage, or who pay for prescription drugs with cash. We note that section 7162 of the SUPPORT for Patients and Communities Act also supports PDMP integration as part of the CDC's grant programs aimed at efficiency and enhancement by States, including improvement in the intrastate and interstate interoperability of PDMPs.

In addition, the explanatory statement that accompanied Title II of Division H of the Consolidated Appropriations Act, 2018 (Pub. L. 115–141),[815] encouraged the CDC to work with the ONC to enhance the integration of PDMPs and EHRs. As part of this effort, the CDC and ONC are collaborating to expand upon previous and leverage input from current federal efforts to advance and scale PDMP integration with health IT systems. This collaboration includes testing and refining standard-based approaches to enable effective integration into clinical workflows, exploring emerging technical solutions to enhance access and use of PDMP data, providing technical resources to a variety of stakeholders to advance and scale the interoperability of health IT systems and PDMPs, and incorporating policy considerations, as relevant, to inform the implementation and success of integration approaches.

We understand that there is wide variation across the country in how health care providers are implementing and integrating PDMP queries into health IT and clinical workflows, and that it could be burdensome for health care providers if we were to narrow the measure to allow only a single workflow. At the same time, we have heard extensive feedback from EHR developers that incorporating the ability to count the number of PDMP queries in CEHRT would require more robust certification specifications and standards. These stakeholders state that health IT developers may face significant cost burdens under the current flexibility allowed for health care providers if they either fully develop numerator and denominator calculations for all the potential use cases and are required to change the specification at a later date. Developers have noted that the costs of additional development will likely be passed on to health care providers without additional benefit as this development would be solely for the purpose of calculating the measure rather than furthering the clinical goal of the measure.

Given the stakeholder concerns discussed above regarding the lack of integration, the recent enactment of the SUPPORT for Patients and Communities Act (in particular, its provisions specific to Medicaid providers and qualified PDMPs), and the activities funded by the CDC, we believe that additional time is needed to evaluate the changing PDMP landscape prior to requiring a Query of PDMP measure, or introducing requirements related to EHR–PDMP integration.

Therefore, we are proposing to make the Query of PDMP measure optional in CY 2020 and eligible for 5 bonus points, and we are proposing corresponding changes to the regulations at §§ 495.24(e)(5)(ii)(B) and 495.24(e)(5)(iii)(B). Making the measure optional in CY 2020 would allow time for further integration of PDMPs and EHRs to minimize the burden on eligible hospitals and CAHs reporting this measure while still giving hospitals an opportunity to report on and earn points for the measure. We are proposing that, in the event we finalize the proposed changes to the Query of PDMP measure, the e-Prescribing measure would be worth up to 10 points in CY 2020 and subsequent years, and we are proposing corresponding changes to the regulations at § 495.24(e)(5)(iii)(A).

[815] *https://www.govinfo.gov/content/pkg/CREC-2018-03-22/html/CREC-2018-03-22-pt3-PgH2697.htm.*

In addition, beginning with the EHR reporting period in CY 2019, we are proposing to remove the numerator and denominator that we established for the Query of PDMP measure in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41649 through 41653) and instead require a ''yes/no'' response. Under this proposal, the measure description at § 495.24(e)(5)(iii)(B) and 83 FR 41653 would remain the same, but instead of submitting numerator and denominator information for the measure, eligible hospitals and CAHs would submit a ''yes/no'' response during attestation. A ''yes'' response would indicate that for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH used data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.

We are proposing these changes to the measure to give us more time to restructure the measure and develop a robust measure that meets the needs of both health care providers and other stakeholders. Because currently there are not standards-based interfaces between CEHRT and the PDMPs, health care providers must manually track the number of times that they query the PDMP outside of CEHRT. We are proposing these changes to reduce the burden on health care providers of having to manually keep track of information related to the measure and to mitigate the burden on health IT developers who would otherwise have to develop the measure's numerator and denominator calculations when we expect to propose changes to the measure in the near future. Therefore, health care providers and health IT developers have suggested that, given the current state, there would be a significant reduction in burden by allowing health care providers to satisfy the measure by submitting a ''yes/no'' attestation, rather than reporting a numerator and denominator.

We are also proposing this change to help reduce the burden of manually counting on health care providers and the need to mitigate the burden on developers caused by the developing the measure's numerator and denominator calculations when the measure is expected to be modified in the near future. Health care providers and developers have suggested that, given the current state, there would be a significant reduction in burden by allowing health care providers to satisfy the measure by submitting a ''yes/no'' attestation, rather than reporting a numerator and denominator. We do not believe that these changes would result in additional costs (time or money) for health care providers, and instead would reduce the burden of manually tracking information needed to report on this measures in its current form.

We also are proposing to remove the exclusions associated with the Query of PDMP measure beginning in CY 2020, and we are proposing corresponding changes to the regulations at §§ 495.24(e)(5)(iv) and 495.24(e)(5)(v)(B) through (D). For CY 2019, we did not provide exclusions for the Query of PDMP and Verify Opioid Treatment Agreement measures because they were optional and eligible for bonus points, and similarly, we do not believe exclusions would be necessary for the Query of PDMP measure if we finalize our proposal to make the measure optional and eligible for bonus points in CY 2020.

Finally, we are proposing to address the scoring of the Query of PDMP measure. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41644), we stated that the measure is optional in CY 2019 and worth ''up to 5 bonus points.'' Our intent, however, was to refer to a full 5 bonus points; we did not intend for the optional measure to be scored based on performance in CY 2019. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20522 through 20523), we provided tables illustrating the proposed new scoring methodology and a numerical example of how that scoring methodology would be applied for CY 2019. We referred to these tables again in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41642). The table containing the numerical example demonstrates our intent to award a full 5 bonus points for the measure regardless of the eligible hospital or CAH's performance rate. We are proposing to revise § 495.24(e)(5)(iii)(B) to better reflect our intended policy that the Query of PDMP measure is worth a full 5 bonus points (not up to 5 bonus points) in CY 2019, and in the event we finalize the proposed changes to the Query of PDMP measure discussed above, in CY 2020 as well. In the event we finalize those proposed changes, if an eligible hospital or CAH submits a ''yes'' for this measure, it would earn 5 bonus points in CY 2019 and 2020.

We also welcome comments on future timing for requiring a measure that includes EHR–PDMP integration and on the value of the measure for advancing the effective prevention and treatment of opioid use disorder especially in relation to the requirements of the SUPPORT for Patients and Communities Act described above. Specifically, we are interested in stakeholder comments related to potential opportunities for the Medicare Promoting Interoperability Program to take into account States' Medicaid investments and requirements.

We also note that some stakeholders have asked us to define a value set for controlled substances for the opioid-related measures, Query of PDMP and Verify Opioid Treatment Agreement. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41648 through 41656), for the Query of PDMP and Verify Opioid Treatment Agreement measures, we defined opioids as Schedule II controlled substances under 21 CFR 1308.12. We recognize that some challenges remain related to electronic prescribing of controlled substances, including more restrictive State laws and lack of products both for health care providers and pharmacies that include the necessary functionalities. We anticipate working closely with the DEA on future technical requirements that can better support measurement of adoption and use of electronic prescribing of controlled substances, which may include the definition of a value set related to such measures. As more information on developing technical requirements becomes available, we will provide additional information.

As we seek comment and continue to advance this measure, we are excited about future innovations that may help improve PDMPs and support the electronic prescribing of controlled substances. We envision a future state where PDMP data is integrated into the clinical workflow and where clinicians do not have to access multiple systems to find and reconcile the information. Rather, all the functions would be contained within one system. While we may have a long distance to go to get to this state, we feel that it is an achievable goal for the future of the Medicare Promoting Interoperability Program.

c. Verify Opioid Treatment Agreement Measure

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41653 through 41656), we finalized the Verify Opioid Treatment Agreement measure as optional in both CYs 2019 and 2020. Since we proposed this measure (83 FR 20528 through 20530), we have received feedback from stakeholders that this measure presents significant implementation challenges, leads to an increase in burden, and does not further interoperability. Below, we outline some of the ongoing concerns we have heard during the comment period and since the measure was finalized in the FY 2019 IPPS/LTCH

PPS final rule (83 FR 41653 through 41656).

(1) Lack of Certification Standards and Criteria

Stakeholders have continued to express concern regarding the lack of defined data elements, structure, standards and criteria for the electronic exchange of opioid treatment agreements and how this impacts verifying whether there is an opioid treatment agreement to meet this measure. We acknowledged these concerns in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41653 through 41656).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41654), we stated that there are a number of ways certified health IT may be able to support the electronic exchange of opioid abuse-related treatment data, such as the care plan template within the Consolidated-Clinical Document Architecture (C–CDA). We noted that this information could be considered as part of an opioid treatment agreement, even though we did not define the elements of one. However, we understand that while such standards may include relevant information, the lack of clarity around a specific standard to support incorporation of an opioid treatment agreement presents an additional source of burden to health care providers seeking to report on the measure.

(2) Calculating 30 Cumulative Day Look-Back Period

Another area where stakeholders have expressed concern is how to calculate 30 cumulative days of Schedule II opioid prescriptions in a 6-month period. One possible solution we offered was to utilize the NCPDP 10.6 Medication History query. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41655), we noted that the Medication History query does not contain a discrete field for prescription days and relies on third party data that may not be discrete. Since the FY 2019 IPPS/LTCH PPS final rule was published, stakeholders have continued to express this concern and impress upon us that the 30 cumulative day total in a 6-month look-back period cannot be automatically calculated, requiring health care providers to engage in a burdensome, manual calculation process if they wish to report on this measure.

In addition, we have heard concerns over which medications should be used to determine the 30 cumulative day threshold. For example, stakeholders were unsure if medications given while a patient is admitted to the hospital should count towards the 30 cumulative days and also how as needed, or PRN, medications should be addressed.

Stakeholders have also noted how this measure could present timing challenges. For example, it may cause patients being discharged on opioids to be delayed in their discharge to account for the possible time consuming nature of having to search for an opioid treatment agreement.

(3) Unintended Burden Caused by Lack of Definition and Standards

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41653), we did not define what constitutes an opioid treatment agreement. While we believed that this would allow flexibility for health care providers to determine which elements they felt were most important to an opioid treatment agreement, we have heard from stakeholders that the lack of definition and standards around what would constitute an opioid treatment agreement has created an unintended burden. Specifically, some stakeholders felt that we should define an opioid treatment agreement so that eligible hospitals and CAHs would have a standardized definition of an opioid treatment agreement and the criteria to make up an opioid treatment agreement. However, other stakeholders noted that given the lack of consensus within the industry on what should or should not be included in an opioid treatment agreement and on the clinical efficacy of various options for such agreements, that it would be inappropriate for us to define what should constitute an opioid treatment agreement at this time.

We have heard from stakeholders that the challenges described above result in a measure that is vague, burdensome to measure and does not necessarily offer a clinical value to the health care providers or support the clinical goal of supporting OUD treatment. Therefore, we are proposing to remove the Verify Opioid Treatment Agreement measure from the Promoting Interoperability Program beginning with the EHR reporting period in CY 2020, and we are proposing corresponding changes to the regulations at §§ 495.24(e)(5)(ii)(B) and 495.24(e)(5)(iii)(C).

While we are proposing to remove the Verify Opioid Treatment Agreement measure, we believe there may be other opioid measures that would be more effective in combatting the opioid epidemic, offer value for health care providers in measuring the impacts of health IT-enabled resources on OUD prevention and treatment, and engage patients in care coordination and planning. In section VIII.D.6.b. of the preamble of this proposed rule, we are proposing to adopt two opioid clinical quality measures beginning with the reporting period in CY 2021. We also are seeking public comment on a series of questions regarding new opioid measures in section VIII.D.7.a. and b. of the preamble of this proposed rule.

Finally, we are proposing to address the scoring of the Verify Opioid Treatment Agreement measure. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41644) we stated that the measure is optional in CYs 2019 and 2020 and worth ''up to five bonus points.'' As with the Query of PDMP measure discussed in section VIII.D.3.b. of the preamble of this proposed rule, above, our intent was to refer to a full 5 bonus points; we did not intend for the optional Verify Opioid Treatment Agreement measure to be scored based on performance in CY 2019 or CY 2020. Accordingly, we are proposing to revise § 495.24(e)(5)(iii)(C) to better reflect our intended policy that the Verify Opioid Treatment Agreement measure is worth a full 5 bonus points (not up to 5 bonus points) in CY 2019, and in the event we do not finalize our proposal to remove the measure beginning with CY 2020, in CY 2020 as well.

4. Health Information Exchange Objective: Support Electronic Referral Loops by Receiving and Incorporating Health Information

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41661), we finalized the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. Although the numerator and denominator of the measure state that CEHRT must be used (83 FR 41661), we inadvertently omitted a reference to the use of CEHRT from the measure description in the regulations at § 495.24(e)(6)(ii)(B). In addition, we stated at 83 FR 41660 that an eligible hospital or CAH must use the capabilities and standards for CEHRT at 45 CFR 170.315(b)(1) and (b)(2).

In an effort to more clearly capture the previously established policy, we are proposing to revise the regulations for the Support Electronic Referral Loops by Receiving and Incorporate Health Information measure. We are proposing to revise § 495.24(e)(6)(ii)(B) to provide that the electronic summary of care record must be received using CEHRT and that clinical information reconciliation for medication, medication allergy, and current problem list must be conducted using CEHRT.

5. Proposed Changes to the Scoring Methodology for Eligible Hospitals and CAHs Attesting to CMS Under the Medicare Promoting Interoperability Program for an EHR Reporting Period in CY 2020

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41668), we finalized under § 495.24(e) a new performance-based scoring methodology and changes to the objectives and measures for eligible hospitals and CAHs that submit an attestation to CMS under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019. For more information, we refer readers to that final rule (83 FR 41636 through 41668) and § 495.24(e). As previously discussed in sections VIII.D.3. and 4. of the preamble of this proposed rule, we are proposing for CY 2020 to: (1) Remove the Verify Opioid Treatment Agreement measure; (2) continue the Query of PDMP measure as optional with 5 bonus points; and (3) change the maximum points available for the e Prescribing measure to 10 points beginning in CY 2020, in the event we finalize the proposed changes to the Query of PDMP measure. The tables below reflects the proposed policy for the objectives, measures, and maximum points available for the EHR reporting period in CY 2020. The maximum points available do not include points that would be redistributed in the event that an exclusion is claimed.

PROPOSED PERFORMANCE-BASED SCORING METHODOLOGY EHR REPORTING PERIOD IN CY 2020

Objective	Measure	Maximum points
Electronic Prescribing	e-Prescribing *	10 points.
	Bonus: Query of PDMP *	5 points (*bonus*).
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	20 points.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points.
Public Health and Clinical Data Exchange.	Choose any two: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting • Electronic Reportable Laboratory Result Reporting	10 points.

Note. The Security Risk Analysis measure is required, but will not be scored.
* Measures with proposed changes to scoring are denoted with an asterisk (*).

6. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals (CAHs) Participating in the Medicare and Medicaid Promoting Interoperability Programs

a. Background and Current CQMs

Under sections 1814(l)(3)(A), 1886(n)(3)(A), and 1903(t)(6)(C)(i)(II) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures (referred to as CQMs) selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare and Medicaid Promoting Interoperability Programs.

The table below lists the CQMs available for eligible hospitals and CAHs to report under the Medicare and Medicaid Promoting Interoperability Programs beginning with the reporting period in CY 2020 (83 FR 41670 through 41671).

CQMS FOR ELIGIBLE HOSPITALS AND CAHS BEGINNING WITH CY 2020

ED–2	Admit Decision Time to ED Departure Time for Admitted Patients (ED–2)	0497
PC–05	Exclusive Breast Milk Feeding	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372

b. Proposed Additional CQMs for Reporting Periods Beginning With CY 2021

As we have stated previously in rulemaking (82 FR 38479), we plan to continue to align the CQM reporting requirements for the Promoting Interoperability Programs with similar requirements under the Hospital IQR Program. To do this in a way that would minimize burden, while maintaining a set of meaningful clinical quality measures and continuing to incentivize improvement in the quality of care provided to patients, we are proposing to adopt two new opioid-related clinical quality measures and are seeking comments on whether we should consider proposing to adopt the Hybrid Hospital-Wide Readmission (HWR) Measure with Claims and EHR Data in future rulemaking for the Promoting Interoperability Program.

In this proposed rule, we are proposing to add the following two opioid-related CQMs to the Promoting Interoperability Program measure set beginning with the reporting period in CY 2021: (1) Safe Use of Opioids—Concurrent Prescribing CQM (NQF #3316e); and (2) Hospital Harm—Opioid-Related Adverse Events eCQM.

We are also proposing to adopt these measures under the Hospital IQR Program and we refer readers to the discussion of the Hospital IQR Program in sections VIII.A.5.a. of the preamble of this proposed rule for more information about these proposed measures.

We believe these opioid-related measures are valuable patient safety measures and are responsive to stakeholder feedback expressing support for CQMs that focus on higher priority measurement areas and patient outcomes. While both measures are designed to reduce adverse events or harms associated with opioid use, the main focus of each measure's intent is different.

The Safe Use of Opioids—Concurrent Prescribing CQM (NQF #3316e) seeks to reduce preventable mortality and the costs of adverse events associated with opioid use by encouraging heath care providers to identify patients who have concurrent prescriptions for opioids or opioids and benzodiazepines, and discouraging health care providers from prescribing these drugs concurrently, whenever possible. Concurrent prescriptions of opioids or opioids and benzodiazepines place patients at a greater risk of unintentional overdose due to the increased risk of respiratory depression. Therefore, we are proposing to adopt the Safe Use of Opioids—Concurrent Prescribing CQM (NQF #3316e) beginning with the reporting period in CY 2021. The Safe Use of Opioids—Concurrent Prescribing CQM seeks to encourage health care providers to identify patients who have concurrent prescriptions for opioids or opioids and benzodiazepines, and discourage health care providers from prescribing these drugs concurrently, whenever possible. The goal of the measure is to provide a patient-centric measure to help systems identify and monitor patients at risk, and, ultimately, reduce the risk of harm to patients across the continuum of care.

The Hospital Harm—Opioid-Related Adverse Events eCQM is designed to reduce adverse events associated with the administration of opioids in the hospital setting by assessing the administration of naloxone as an indicator of harm. Implementation of the measure can lead to safer patient care by incentivizing hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and to avoid harm, such as respiratory depression, which can lead to brain damage and death. This EHR-based measure focuses, specifically, on in-hospital opioid-related adverse events, by requiring evidence of hospital opioid administration, prior to the naloxone administration, during the first 24 hours after hospital arrival. This ensures that the harm was hospital-acquired and not due to an overdose that happened outside of the hospital. We believe that this measure will provide hospitals with reliable and timely measurement of their opioid-related adverse event rates, which is a high-priority measurement area, and therefore we are proposing to adopt the Hospital Harm—Opioid-Related Adverse Events eCQM beginning with the reporting period in CY 2021.

We acknowledge that some stakeholders have expressed concern that some providers could withhold the use of naloxone for patients who are in respiratory depression, believing that may help those providers avoid poor performance on the proposed Hospital Harm—Opioid-Related Adverse Events eCQM (83 FR 41591). Therefore, we are soliciting public comment on the potential for this measure to disincentivize the appropriate use of naloxone in the hospital setting or withholding opioids when they are medically necessary in patients requiring palliative care or who are at end of life out of an overabundance of caution.

c. Request for Information (RFI) Regarding Potential Adoption of the Hybrid Hospital-Wide Readmission (HWR) Measure With Claims and EHR Data (Hybrid HWR Measure) for Reporting Periods Beginning With CY 2023

We refer readers to section VIII.A.5.b. of the preamble of this proposed rule for a discussion of our proposals under the Hospital IQR Program to adopt the Hybrid Hospital-Wide Readmission (HWR) Measure with Claims and EHR Data, beginning with the July 1, 2023 through June 30, 2024 reporting period. The Hybrid HWR measure is designed to capture all unplanned readmissions that arise from acute clinical events requiring urgent re-hospitalization within 30 days of discharge, and it provides a facility-wide picture of this aspect of care quality for Medicare fee-for-service (FFS) beneficiaries who are 65 years or older and hospitalized in non-federal hospitals. In addition, the measure reports a single summary risk-standardized readmission rate (RSRR) of unplanned, all-cause readmission within 30 days of hospital discharge for any eligible condition, and indicates the hospital-level standardized readmission ratios (SRR) for each category. The discharge condition categories or procedure categories for this measure are: (1) Surgery/gynecology; (2) general medicine; (3) cardiorespiratory; (4) cardiovascular; and (5) neurology.

We are seeking comment on whether we should consider proposing to adopt the Hybrid HWR CQM in future rulemaking for the Promoting Interoperability Program starting with the reporting period in CY 2023. We note that the Hospital IQR Program, as discussed in sections VIII.A.5.b. and VIII.A.10.e. of the preamble of this proposed rule, is proposing that this Hybrid HWR measure be required with the reporting period from July 1, 2023 through June 30, 2024. The 12-month measurement period that runs from July 1 through June 30 is consistent with the calculation of the Hospital IQR Program's current HWR claims-only measure; however, it does not align with the reporting period for CQMs, which is one self-selected calendar quarter.

d. Proposed CQM Reporting Periods and Criteria for the Medicare and Medicaid Promoting Interoperability Programs in CY 2020, 2021, and 2022

(1) Proposed CQM Reporting Periods and Criteria in CY 2020 and 2021

For CY 2020 and 2021, we are proposing generally the same CQM reporting periods and criteria as established in the FY 2019 IPPS/LTCH PPS final rule for the Medicare and Medicaid Promoting Interoperability Programs in CY 2019 (83 FR 41671). We are proposing that the CQM reporting period and criteria under the Medicare and Medicaid Promoting Interoperability Programs for eligible hospitals and CAHs reporting CQMs electronically would be as follows: For eligible hospitals and CAHs participating only in the Promoting Interoperability Program, or participating in the both Promoting Interoperability Program and the Hospital IQR Program, report one, self-selected calendar quarter of data for four self-selected CQMs from the set of available CQMs. We are proposing the following reporting criteria for eligible hospitals and CAHs that report CQMs by attestation under the Medicare Promoting Interoperability Program as a result of electronic reporting not being feasible—report on all CQMs from the set of available CQMs. For eligible hospitals and CAHs that report CQMs by attestation, we previously established a CQM reporting period of the full CY (consisting of 4 quarterly data reporting periods) (80 FR 62893).

We are proposing a submission period for the Medicare Promoting Interoperability Program that would be the 2 months following the close of the calendar year, ending February 28, 2021

(for the CQM reporting period in CY 2020) and February 28, 2022 (for the CQM reporting period in CY 2021). With regard to the Medicaid Promoting Interoperability Program, we provide States with the flexibility to determine the method of reporting CQMs (attestation or electronic reporting) and the submission periods for reporting CQMs, subject to prior approval by CMS.

We believe that continuing the same CQM reporting and submission requirements is appropriate because it continues to offer hospitals reporting flexibility and does not increase the information collection burden on data submitters. In addition, we believe that alignment with the requirements of the Hospital IQR program reduces burden for hospitals as they may report once and fulfill the requirements of both programs.

(2) Proposed CQM Reporting Periods and Criteria in CY 2022

For CY 2022, we are proposing that the CQM reporting period and criteria under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs reporting CQMs electronically would be as follows—for eligible hospitals and CAHs participating only in the Promoting Interoperability Program or participating in both the Promoting Interoperability Program and in the Hospital IQR Program, report one, self-selected calendar quarter of data for: (a) Three self-selected CQMs from the set of available CQMs; and (b) the proposed Safe Use of Opioids—Concurrent Prescribing CQM (NQF #3316e), for a total of four CQMs. Under this proposal, we would not change the number of CQMs that hospitals must report while ensuring that health care providers still have meaningful choice among the set of available CQMs. We are proposing the following reporting criteria for eligible hospitals and CAHs that report CQMs by attestation under the Medicare Promoting Interoperability Program as a result of electronic reporting not being feasible—report on all CQMs from the set of available CQMs. For eligible hospitals and CAHs that report CQMs by attestation, we previously established a CQM reporting period of the full CY (consisting of 4 quarterly data reporting periods) (80 FR 62893).

We are proposing that the submission period for the Medicare Promoting Interoperability Program would be the 2 months following the close of the calendar year 2022, ending February 28, 2023.

We also refer readers to section VIII.A.10.d. of the preamble of this proposed rule for the reporting and submission requirements associated with the proposal to add the Safe Use of Opioids—Concurrent Prescribing CQM (NQF #3316e) to the measure set for the Hospital IQR Program.

e. CQM Reporting Form and Method Requirements for the Medicare Promoting Interoperability Program in CY 2020

(1) Requiring EHR Technology To Be Certified to All Available CQMs

We are proposing to continue requiring that EHRs be certified to all available CQMs adopted for the Medicare Promoting Interoperability Program for CY 2020 and subsequent years. This policy was previously finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38483 through 38485) for CY 2018 and in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41671 through 41672) for CY 2019. We require this so that eligible hospitals and CAHs have flexibility in selecting the CQMs to report that best reflect their patient populations and reporting capabilities. In addition, this requirement would produce greater certainty for eligible hospitals and CAHs that their EHR systems would be capable of accurately calculating the particular CQMs they select to report to CMS. Because this is the current policy for the Hospital IQR and Medicare Promoting Interoperability Programs, vendors and health care providers should be familiar with this requirement, and their EHR systems should already be certified to all currently available CQMs.

We refer readers to section VIII.A.10.d.(5)(B) of the preamble of this proposed rule for a similar proposal for hospitals under the Hospital IQR Program.

(2) Other CQM Form and Method Requirements

As we stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759 through 49760), for the reporting periods in 2016 and future years, we are requiring QRDA–I for CQM electronic submissions for the Medicare EHR Incentive (now Promoting Interoperability) Program. As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49760), States would continue to have the option, subject to our prior approval, to allow or require QRDA–III for CQM reporting.

The form and method of electronic submission are further explained in subregulatory guidance and the certification process. For example, the following documents are updated annually to reflect the most recent CQM electronic specifications: The CMS Implementation Guide for QRDA; program specific performance calculation guidance; and CQM electronic specifications and guidance documents. These documents are located on the eCQI Resource Center web page at: *https://ecqi.healthit.gov/*. For further information on CQM reporting, we refer readers to the EHR Incentive Program (now Promoting Interoperability Program) website where guides and tip sheets are located at: *http://www.cms.gov/ehrincentiveprograms.*

For the reporting period in CY 2020, we are proposing the following for CQM submission under the Medicare Promoting Interoperability Program:

- Eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program (single program participation)—electronically report CQMs through QualityNet Portal.
- Eligible hospital and CAH options for electronic reporting for multiple programs (that is, Promoting Interoperability Program and Hospital IQR Program participation)—electronically report through QualityNet Portal.

As noted in the 2015 EHR Incentive Programs final rule (80 FR 62894), starting in 2018, eligible hospitals and CAHs participating in the Medicare EHR Incentive Program must electronically report CQMs where feasible; and attestation to CQMs will no longer be an option except in certain circumstances where electronic reporting is not feasible. For the Medicaid Promoting Interoperability Program, States continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any changes that States make to their CQM reporting methods must be submitted through the State Medicaid Health IT Plan (SMHP) process for CMS review and approval prior to being implemented.

For CY 2020, we are proposing to continue our policy regarding the electronic submission of CQMs, which requires the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified. For the CY 2020 electronic reporting of CQMs, this means eligible hospitals and CAHs are required to use the 2018 CQM specifications update (published in May 2018) and any applicable addenda available on the eCQI Resource Center web page at: *https://ecqi.healthit.gov/*. As noted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41635 through 41636), participants are required to use

2015 Edition CEHRT for the Medicare and Medicaid Promoting Interoperability Programs, beginning with the EHR reporting period in CY 2019. We reiterate that an EHR certified for CQMs under the 2015 Edition certification criteria does not have to be recertified each time it is updated to a more recent version of the CQMs (82 FR 38485).

(3) Proposed Modification to Reporting Methods for CQMs Beginning With the Reporting Period in CY 2023

We currently allow eligible hospitals and CAHs to report CQMs by attestation for the Medicare Promoting Interoperability Program only in certain circumstances where electronic reporting is not feasible (80 FR 62893 through 62894). Beginning with the CQM reporting period in CY 2023, we are proposing to eliminate attestation as a method for reporting CQMs for the Medicare Promoting Interoperability Program and instead require all eligible hospitals and CAHs to submit their CQM data electronically through the reporting methods available for the Hospital IQR Program. We believe that data submitted electronically is preferable so that we can use the data to analyze trends across hospitals and further refine quality data in the future. Limiting the available reporting methods to electronic submission would enable us to have a more robust data set so that we can ensure that hospitals are delivering effective, safe, efficient, patient-centered, equitable, and timely care. Also, we believe that we are allowing an adequate transition period for eligible hospitals and CAHs to migrate to electronic submission.

7. Future Direction of the Promoting Interoperability Program

a. Request for Information (RFI) on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability Program

In the past, the Promoting Interoperability Program measures focused on very general process focused actions supported by health IT. In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62766 through 62768), we sought to expand the potential for Medicare and Medicaid Promoting Interoperability Program measures to include more complex measures and closer relationships to high priority health outcomes.

In this RFI, we are seeking comment on Promoting Interoperability program measures in addition to the CQMs we are proposing to adopt in section VIII.D.6.b. of the preamble of this proposed rule ((1) Safe Use of Opioids—Concurrent Prescribing CQM (NQF #3316e); and (2) Hospital Harm—Opioid-Related Adverse Events eCQM) that might be relevant to specific clinical priorities or goals related to addressing OUD prevention and treatment. As the Query of PDMP measure matures, we believe it will be essential in improving prescribing practices. As outlined in section VIII.D.3.c. of the preamble of this proposed rule, stakeholders indicated that the Verify Opioid Treatment Agreement measure presented significant implementation challenges for eligible hospitals and CAHs. Therefore, we are seeking comment on potential new measures for OUD prevention and treatment that could be included in future years of the Promoting Interoperability Program. We welcome all comments, but we are seeking comment specifically on possible OUD prevention and treatment measures that include the following characteristics:

- Are applicable to all hospital settings (for example, rural, urban, small hospitals, large hospitals);
- Are represented by a measure description, numerator/denominator or ''yes/no'' attestation statement, and possible exclusions;
- Include evidence of positive impact on outcome-focused improvement activities, and the opioid crisis overall;
- Leverage the capabilities of CEHRT, including: automatic calculation and reporting of numerator, denominator, exclusions and exceptions, and timing elements to reduce quality measurement and reporting burdens to the greatest extent possible;
- Are based on well-defined clinical concepts, measure logic and timing elements that can be captured by CEHRT in standard clinical workflow and/or routine business operations. Well-defined clinical concepts include those that can be discretely represented by available clinical and/or claims vocabularies such as SNOMED CT, LOINC, RxNorm, ICD–10 or CPT; and
- Align with clinical workflows in such a way that data used in the calculation of the measure is collected as part of a standard workflow and does not require any additional steps or actions by the health care provider.

b. Request for Information (RFI) on NQF and CDC Opioid Quality Measures

We also are specifically seeking public comment on the development of potential measures for consideration for the Promoting Interoperability Program that are based on existing efforts to measure clinical and process improvements specifically related to the opioid epidemic, including the opioid quality measures endorsed by the National Quality Forum (NQF) and the CDC Quality Improvement (QI) opioid measures discussed below. The NQF measures represent a reference point for evaluating opioid prescribing behaviors based on measures that have undergone the rigorous NQF measure endorsement process. The CDC guidelines ''encourage careful and selective use of opioid therapy in the context of managing chronic pain through . . . an evidence-based prescribing guideline.'' [816] The guidelines have led to the development of CDC measures on prescribing practices on which are seeking comment. We believe that these measures may help participants understand the relationship between the measure description and the use of health IT to support the actions of the measures.

For example, the measures may describe a clinical concept, such as the CDC Measure 12: Counsel on Risks and Benefits Annually. The actions for this activity can be supported by CEHRT through the use of standards to record key health information for the patient and to identify which patients should be included in the denominator based on information in the medication list, information gained through medication reconciliation of data received through health information exchange with another health care provider, and/or information incorporated after a query of a PDMP is completed. The actions for the numerator could include leveraging CEHRT to provide patient-specific education, to capture or record Patient-Generated Health Data (PGHD), to engage in secure messaging with the patient and ensure the patient is engaging with their record through a patient portal or an API.

We believe that the clinical actions identified within both the NQF quality measures and the CDC QI opioid measures can be supported by the standards and functionalities of certified health IT and we welcome public comment on the specific use cases for health IT implementation for the potential measure actions. We recognize that modifications to the NQF and CDC measures may be necessary to make the measures as applicable as possible to all participants of the Promoting Interoperability Program, and are

[816] *https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf.*

seeking comment on any modifications that would be necessary. In addition, we note that there is some overlap between some of the NQF quality measures and the CDC QI opioid measures and are seeking comment on whether there are ways in which the two sets of measures could be correlated to support potential new measures of the meaningful use of health IT for the Promoting Interoperability Programs. Finally, we are seeking comment on which measures might best advance the implementation and use of interoperable health IT and encourage information exchange between care teams and with patients.

(1) NQF Quality Measures

Three NQF-endorsed quality measures stewarded by the Pharmacy Quality Alliance (PQA) to evaluate patients with prescriptions for opioids in combination with benzodiazepines, at high-dosage, or from multiple prescribes and pharmacies. Each measure was evaluated and recommended for endorsement by the NQF's Patient Safety Standing Committee [817] and endorsed by the Consensus Standards Approval Committee.[818] These measures, NQF #2940, #2950, and #2951 were recommended by the NQF Measure Application Partnership for inclusion on the December 2018 Measures Under Consideration List for the Medicare Shared Savings Program. (As noted in section VIII.D.6.b. of the preamble of this proposed rule, we are also proposing to add two opioid-related CQMs to the Promoting Interoperability Program CQM measure set beginning with the reporting period in CY 2021, including the NQF-endorsed measure, Safe Use of Opioids—Concurrent Prescribing (NQF #3316e), a CQM.) We are seeking comment on the following three NQF measures for possible inclusion in the Promoting Interoperability Program and any modifications that may be necessary to maximize their use in the Promoting Interoperability Program:

- Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940).
- Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950).
- Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer (NQF #2951).

We believe these measures relate to activities that hold promise in combatting the opioid epidemic and can be supported using CEHRT to complete the actions of the measures and are seeking comment on the best method to incorporate the description of the use of technology into measure guidance if these measures were considered for use by participants. For example, the actions related to the Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950) measure could include using health IT to electronically prescribe the medication, to query a PDMP, to identify other care team members, to conduct medication reconciliation based on information received through health information exchange with other health care providers, and recording key health information in a structured format. Additional information regarding each measure can be found using NQF's Quality Positioning System at: *http://www.qualityforum.org/QPS/QPSTool.aspx.*

(2) CDC Quality Improvement (QI) Opioid Measures

We believe there may be promise in the CDC QI opioid measures based on the prescribing best practices found in Appendix B in the CDC document ''Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain'' (Implementing the CDC Prescribing Guideline).[819]

CDC developed its Implementing the CDC Prescribing Guideline document to help health care providers and systems integrate the CDC Prescribing Guideline [820] and the associated QI opioid measures found in the Implementing the CDC Prescribing Guideline document into their clinical practices. The CDC developed 16 QI opioid measures to align with the recommendations in the CDC Prescribing Guideline and to improve opioid prescribing. These measures are intended to provide healthcare systems tracking of their implementation of the recommended practices. We believe this is generally consistent with the to the objective and measure concept of the Promoting Interoperability Program where the recommendation in the CDC Prescribing Guideline is the overarching objective and the QI opioid measure is a description of the patient population focus (denominator) and the desired action (numerator). The Implementing the CDC Prescribing Guideline document also includes practice-level strategies to help organize and improve the management and coordination of long-term opioid therapy:

- Using an interdisciplinary team approach.
- Establishing practice policies and standards.
- Using EHR data to develop registries and track QI opioid measures.

These measures address treatment guidelines for both initial treatment practices and long-term treatment and outcomes. Examples of measures related to short term OUD prevention and treatment activities include:

- CDC Measure 2: Check PDMP Before Prescribing Opioids.
- CDC Measure 4: Evaluate Within Four Weeks of Starting Opioids.

Examples of measures related to long term OUD prevention and treatment activities include:

- CDC Measure 11: Check PDMP Quarterly.
- CDC Measure 12: Counsel On Risks and Benefits Annually.

The data sources from these measures include State PDMP data or the practice EHR data field.

The CDC and the Agency for Healthcare Research and Quality are also developing electronic clinical decision support tools which can provide real-time clinical decision support (CDS) for some of the best practices included in the Implementing the CDC Prescribing Guideline document.[821] In the context of quality improvement measures, components of these CDS artifacts, including the clinical conditions or prescribed medications that trigger the decision support are the same well-defined clinical concepts required for developing quality improvement measures for the Promoting Interoperability Program related to OUD prevention and treatment. This creates a tight linkage between the guidelines, the recommended clinical actions based on the guidelines, and the improved outcomes based on the recommended clinical actions.

Therefore, we are seeking comment on which of the 16 CDC QI opioid measures have value for potential consideration for the Promoting Interoperability Program. We are further seeking comment on whether we should consider a different type of measurement concept for the OUD prevention and treatment measures, such as reporting on a set of cross cutting activities and measures to earn credit in the Promoting Interoperability Program (for example, a set of one CDS,

[817] *https://www.qualityforum.org/News_And_Resources/Press_Releases/2017/NQF_Statement_on_Endorsement_of_Opioid_Patient_Safety_Measures.aspx.*

[818] Ibid.

[819] *https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf.*

[820] *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.*

[821] *https://cds.ahrq.gov/cdsconnect/topic/opioids-and-pain-management.*

the related CDC QI opioid measure, and a potentially relevant clinical quality measure).

We refer readers to Implementing the CDC Prescribing Guideline document and the related measures available in Appendix B of that document available at: *https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovement AndCareCoordination-508.pdf.*

c. Request for Information (RFI) on a Metric To Improve Efficiency of Providers Within EHRs

One of the benefits of adopting EHRs is increasing the efficiency of health care processes and generating cost savings by eliminating time-consuming paper-based processes. Through the use of EHRs, health care providers are able to automate administrative aspects of delivery system management such as coding and scheduling, easily locate patient information in electronic charts, and streamline communications with other health care providers through electronic means.

However, research also points to variable results from the implementation of health IT across practice settings, suggesting health IT adoption is not a universal remedy for inefficient practice. Stakeholders continue to describe ways in which the potential benefits of EHRs have not been fully realized, pointing to non-optimized electronic workflows and poor system design that can increase rather than reduce administrative burden, contributing to physician burnout.[822] We believe in the value of EHRs in today's health care environment and understand the way forward must include reductions in persistent sources of technology-related burden, and more effective use of technology to achieve true efficiency gains.

In November 2018, ONC released the draft report ''Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs,'' [823] as required by section 4001 of the 21st Century Cures Act. In the draft report, ONC describes a variety of factors that may contribute to EHR-related burden, and provides draft recommendations for how HHS as well as other stakeholders may be able to address these factors. Specifically, the draft report discusses processes where adoption of improved electronic processes could reduce EHR-related burden, such as processes related to prior authorization requests. The draft report also discusses EHR usability and design challenges which may contribute to EHR-related burden, and identifies best practices for design, as well as a variety of emerging system features which may improve efficiency in health IT usage. We believe further adoption of more efficient workflows and technologies such as those identified in the draft report will help health care providers with overall improvements in patient care and interoperability, and we are seeking comment on how such implementation of such processes can be effectively measured and encouraged as part of the Promoting Interoperability Program.

We are also interested in comments regarding how to measure and incentivize efficiency as it relates to the meaningful use of CEHRT and the furthering of interoperability. In 2017, the NQF released ''A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy,'' [824] which included discussion of measure concepts of productivity and efficiency, which can result from the use of health IT, specifically health information exchange. For instance, the NQF report identifies a measure concept for the ''percentage of reduction of duplicate labs and imaging over time,'' which could capture the impact of electronic availability of imaging studies on duplicative studies that are often conducted when health care providers do not have the ability to locate an existing study. However, we recognize that there are challenges associated with tying such measures of economic efficiency to a single factor such as electronic workflow improvements.[825]

Consistent with our commitment to reducing administrative burden, increasing efficiencies, and improving beneficiary experience via the Patients over Paperwork initiative,[826] we are seeking stakeholder feedback on a potential metric to evaluate health care provider efficiency using EHRs. Specifically, we are looking at the following questions:

- What do stakeholders believe would be useful ways to measure the efficiency of health care processes due to the use of health IT? What are measurable outcomes demonstrating greater efficiency in costs or resource use that can be linked to the use of health IT-enabled processes? This includes measure description, numerator/denominator or ''yes/no'' reporting, and exclusions.
- What are specific technologies, capabilities, or system features (beyond those currently addressed in the Promoting Interoperability Program) that can increase the efficiency of health care provider interactions with technology systems, for instance, alternate authentication technologies that can simplify health care provider logon? How could we reward health care providers for adoption and use of these technologies?
- What are key administrative processes that could benefit from more efficient electronic workflows, for instance, conducting prior authorization requests? How could we measure and reward health care providers for uptake of more efficient electronic workflows?

d. Request for Information (RFI) on Including Medicare Promoting Interoperability Program Data on the *Hospital Compare* Website

As the Medicare Promoting Interoperability Program continues to evolve, we are seeking comment on posting Medicare Promoting Interoperability Program measure(s) on the *Hospital Compare* website.

Section 1886(n)(4)(B) of the Act requires the Secretary to post in an easily understandable format a list of the names and other relevant data, as determined appropriate by the Secretary, of eligible hospitals and CAHs who are meaningful EHR users under the Medicare FFS program, on a CMS website. In addition, section 1886(n)(4)(B) of the Act requires the Secretary to ensure that an eligible hospital or CAH has the opportunity to review the other relevant data that are to be made public with respect to the eligible hospital or CAH prior to such data being made public. We believe an eligible hospital or CAH's performance rate on one or more of the Medicare Promoting Interoperability Program measures would constitute other relevant data because it would help consumers make informed decisions regarding their health care team, such as knowing whether and to what extent their health care provider is involved in health information exchange or providing patients with electronic access to their health information.

As we considers posting information regarding the Medicare Promoting Interoperability Program measures in

[822] *https://www.ahrq.gov/professionals/clinicians-providers/ahrq-works/burnout/index.html.*

[823] *https://www.healthit.gov/sites/default/files/page/2018-11/Draft%20Strategy%20on%20Reducing%20Regulatory%20and%20Administrative%20Burden%20Relating.pdf.*

[824] *https://www.qualityforum.org/Publications/2017/09/Interoperability_2016-2017_Final_Report.aspx.*

[825] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699907/.*

[826] *https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html.*

the future, we are seeking comment on the following:

- Of the six required measures and one bonus measure that would apply for an EHR reporting period in CY 2020, how many and which ones should we consider posting?
- What process should be in place to allow eligible hospitals and CAHs the opportunity to review the data prior to publication? This includes comment on how many days the preview period should be for eligible hospitals and CAHs to review data prior to publication and a correction process for those who may have identified an error in their data.
- We are seeking comment on posting the data on the our *Hospital Compare* website, found at: *www.medicare.gov/hospitalcompare.*[827]

e. Request for Information (RFI) on the Provider to Patient Exchange Objective

In March 2018, the White House Office of American Innovation and the CMS Administrator announced the launch of MyHealthEData, and our role in improving patient access and advancing interoperability. As part of the MyHealthEData initiative, we are taking a patient-centered approach to health information access and moving to a system in which patients have immediate access to their computable health information and can be assured that their health information will follow them as they move throughout the health care system from provider to provider, payer to payer. To accomplish this, we have launched several initiatives related to data sharing and interoperability to empower patients and encourage plan and provider competition. One example is our overhaul of the EHR Incentive Program and Advancing Care Information performance category under the MIPS to create the new Promoting Interoperability programs, which put a heavy emphasis on patient access to their health information through the Provide Patients Electronic Access to Their Health Information measure.

Through the Provide Patients Electronic Access to Their Health Information measure, we are ensuring that patients have access to their information through any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the eligible hospital or CAH's CEHRT. To make these APIs fully useful to patients, they should provide immediate access to updated information whenever the patient needs that information, should be always available, configured using standardized technology and contain the information a patient needs to make informed decisions about their care.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20537 through 20538), we introduced a potential future Promoting Interoperability Program concept which explored creating a set of priority health IT activities that would serve as alternatives to the traditional Promoting Interoperability Program measures. We specifically noted that the 21st Century Cures Act requires HHS to take steps to enable the electronic sharing of health information, including helping to ensure interoperability for health care providers and settings across the care continuum. We requested public comment on whether eligible hospitals and CAHs should earn credit by attesting to health IT or interoperability activities in lieu of reporting on specific measures. We identified specific health IT activities and sought public comment on those and additional activities that would add value for patients and health care providers, are relevant to patient care and clinical workflows, support alignment with existing objectives, promote flexibility, are feasible for implementation, are innovative in the use of health IT, and promote interoperability. We received feedback in support of this future concept.

One such activity we specifically requested comment on was a health IT activity in which eligible hospitals and CAHs could obtain credit in the Promoting Interoperability Program if they maintain an ''open API,'' or standards-based API, which allows patients to access their health information through a preferred third party application. An API can be thought of as a set of commands, functions, protocols, or tools published by one software developer (''developer A'') that enables other software developers to create programs (applications or ''apps'') that can interact with developer A's software without needing to know the internal workings of developer A's software, all while maintaining consumer privacy data standards. This is how API technology enables the seamless user experiences associated with applications familiar from other aspects of many consumers' daily lives, such as travel and personal finance. Standardized, transparent, and pro-competitive API technology can enable similar benefits to consumers of health care services.[828]

We received feedback from several commenters regarding concerns that an ''open'' API may open the door to patient data without security, leaving eligible hospitals and CAHs' EHR systems open for cyber-attacks. We wish to note, however, that the term ''open API'' does not imply that any and all applications or application developers would have unfettered access to individuals' personal or sensitive information nor would it allow for any reduction in the required protections for privacy and security of patient health information. In addition, with respect to patient access, a patient will need to authenticate themselves to a health care organization that is the steward of their data (for example, username and password) and the access provided to an app will be for that one patient. The overall HIPAA Security Rule and other cybersecurity obligations that apply to HIPAA Covered Entities remain the same and would need to be applied to an API in the same way they are currently applied to any and all other interfaces a health care organization deploys in production.

ONC's 21st Century Cures Act proposed rule (84 FR 7424 through 7610) includes new proposals that focus on how certified health IT can use APIs to allow health information to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law. For instance, ONC has proposed to adopt a new criterion for a standards-based API at § 170.315(g)(10). This standards-based API criterion would replace the existing API criterion with one that requires the use of the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard. ONC has also proposed a series of requirements for the standards-based API that would improve interoperability by focusing on standardized, transparent, and pro-competitive API practices.

ONC has proposed to make the standards-based API criterion part of the 2015 Edition base EHR definition, which would ensure that this functionality is ultimately included in the CEHRT definition required for participation in the Promoting Interoperability Program. If finalized, ONC has proposed that health IT

[827] *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/hospitalcompare.html.*

[828] ONC has made available a succinct, non-technical overview of APIs in context of consumers' access to their own medical information across multiple providers' EHR systems, which is available at the HealthIT.gov website at: *https://www.healthit.gov/api-education-module/story_html5.html.*

developers would have 24 months from the publication of the final rule to implement these changes to certified health IT products.

(1) Immediate Access

The existing Provide Patients Electronic Access to Their Health Information measure specifies that the eligible hospital or CAH provide the patient timely access to view online, download, and transmit his or her health information, and further specifies that patient health information must be made available to the patient within 36 hours of its availability to the eligible hospital or CAH. We believe it is critical for patients to have access to their health information when making decisions about their care. In the recently published Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers proposed rule (84 FR 7610 through 7680), (hereinafter referred to as the CMS Interoperability and Patient Access proposed rule), we proposed that certain health plans and payers be required to make patient health information available through an open, standards-based API no later than one business day after it is received by the health plan or payer.

Recognizing the importance of patients having access to their complete health information, including clinical information from the eligible hospital or CAH's CEHRT, and appreciating the new technical flexibility a standards-based API provides, we are seeking comment on whether eligible hospitals and CAHs should make patient health information available immediately through the open, standards-based API, no later than one business day after it is available to the eligible hospital or CAH in their CEHRT. We are also seeking comment on the barriers to more immediate access to patient information. And, we are seeking comment on if there are specific data elements that may be more or less feasible to share no later than one business day.

(2) Persistent Access and Standards-Based APIs

As discussed above, the ONC 21st Century Cures Act proposed rule (84 FR 7479), includes a proposal for adoption of API conditions of certification that ensure a standards-based API is implemented in a manner that provides unimpeded access to technical documentation, is non-discriminatory, preserves rights of access, and minimizes costs or other burdens that could result in special effort. The ONC 21st Century Cures Act proposed rule (84 FR 7575), also includes requirements for the standardized API related to privacy and security to ensure that patient health information is protected.

The existing Provide Patients Electronic Access to Their Health Information measure does not specify the overall operational expectations associated with enabling patients' access to their health information. For instance, the measure only specifies that access must be ''timely.'' As a result, we are requesting public comment on whether we should revise the measure to be more specific with respect to the experience, patients should have regarding their access. For instance, in the ONC 21st Century Cures Act proposed rule (84 FR 7481 through 7484) there is a proposal regarding requirements around persistent access to APIs, which would accommodate a patient's routine access to their health information without needing to reauthorize their app and re-authenticate themselves. We are seeking comment on whether the Promoting Interoperability Program measure should be updated to reinforce this proposed technical requirement for persistent access.

As we work to advance interoperability and empower patients through access to their health information, we continue to explore the role of APIs. We support ONC's 21st Century Cures Act proposed rule (84 FR 7424) proposal to move to an HL7 FHIR®-based API under 2015 Edition certification (84 FR 7479). Health care providers committed to a standards-based API could benefit from joining in on the industry's new FHIR standards framework to reduce burden in, and improve on, quality measurement through automation and simplification. Use of FHIR-based APIs could help push forward interoperability regardless of EHR systems used providing standardized way to share information.

Understanding this, we are, specifically, seeking public comment on the following question: If ONC's proposal for a FHIR-based API certification criteria is finalized, would stakeholders support a possible bonus under the Promoting Interoperability Programs for early adoption of a certified FHIR-based API in the intermediate time before ONC's final rule's compliance date for implementation of a FHIR standard for certified APIs?

(3) Available Data

Recognizing the overall burden that switching EHR systems places on health care providers, ONC has introduced a new proposal that seeks to minimize that burden. In the 21st Century Cures Act proposed rule (84 FR 7424 through 7610), ONC has proposed to adopt a new 2015 Edition certification criterion for the Electronic Health Information (EHI) export in 45 CFR 170.315(b)(10). The purpose of this criterion is to provide patients and health IT users the ability to securely export the entire electronic health record for a single patient, or all patients, in a computable, electronic format, and facilitate receiving the health IT system's interpretation, and use of the EHI, to the extent that is reasonably practicable using the existing technology of developers. This patient-focused export capability complements other provisions of the proposed rule that support patients' access to their EHI, including information that may eventually be accessible via the proposed standardized API in 45 CFR 170.215. It is also complementary to the proposals in the CMS Interoperability and Patient Access proposed rule, which has proposed to require certain health plans under CMS to provide patients access to their health data through a standardized API.

Building on these proposals, we are seeking comment on an alternative measure under the Provider to Patient Exchange objective that would require health care providers to use technology certified to the EHI criteria to provide the patient(s) their complete electronic health data contained within an EHR.

Specifically, we are seeking comment on the following questions:

- Do stakeholders believe that incorporating this alternative measure into the Provider to Patient Exchange objective will be effective in encouraging the availability of all data stored in health IT systems?
- In relation to the Provider to Patient Exchange objective as a whole, how should a measure focused on using the proposed total EHI export function in CEHRT be scored?
- If this certification criterion is finalized and implemented, should a measure based on the criterion be established as a bonus measure? Should this measure be established as an attestation measure?
- In the long term, how do stakeholders believe such an alternative measure would impact burden?

• What data elements do stakeholders believe are of greatest clinical value or would be of most use to health care providers to share in a standardized electronic format if the complete record was not immediately available?

In addition to the above questions, we have some general questions that are related to health IT activities, for which we are also seeking public comment:

• Do stakeholders believe that we should consider including a health IT activity that promotes engagement in the health information exchange across the care continuum that would encourage bi-directional exchange of health information with community partners, such as post-acute care, long term care, behavioral health, and home and community based services to promote better care coordination for patients with chronic conditions and complex care needs? If so, what criteria should we consider when implementing a health information exchange across the care continuum health IT activity in the Promoting Interoperability Program?

• What criteria should we employ, such as specific goals or areas of focus, to identify high priority health IT activities for the future of the program?

• Are there additional health IT activities we should consider recognizing in lieu of reporting on existing measures and objectives that would most effectively advance priorities for nationwide interoperability and spur innovation?

(4) Patient Matching

ONC has stated that patient matching is critically important to interoperability and the nation's health IT infrastructure as health care providers must be able to share patient health information and accurately match a patient to his or her data from a different health care provider in order for many anticipated interoperability benefits to be realized. We continue to support ONC's work promoting the development of patient matching initiatives. Per Congress 'guidance, ONC is looking at innovative ways to provide technical assistance to private sector-led initiatives to further develop accurate patient matching solutions in order to promote interoperability without requiring a unique patient identifier (UPI). We understand the significant health information privacy and security concerns raised around the development of a UPI standard and the current prohibition against using HHS funds to adopt a UPI standard.

Recognizing Congress' statement regarding patient matching and stakeholder comments stating that a patient matching solution would accomplish the goals of a UPI, we are seeking comment for future consideration on ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information. We are also seeking comment on how we may leverage our program authority to provide support to those working to improve patient matching. We note that we intend to use comments we receive for the development of policy and future rulemaking.

f. Request for Information (RFI) on Integration of Patient-Generated Health Data Into EHRs Using CEHRT

The Medicare and Medicaid Promoting Interoperability Programs are continuously seeking ways to prioritize the advanced use of CEHRT functionalities, encourage movement away from paper-based processes that increase heath care provider burden, and empower individual beneficiaries to take a more impactful role in managing their health to achieve their goals. Increased availability of patient-generated health data (PGHD) [829] offers health care providers an opportunity to monitor and track a patient's health-related data from information that is provided by the patient and not the provider. Increasingly affordable wearable devices, sensors, and other technologies capture PGHD, providing new ways to monitor and track a patient's healthcare experience. Capturing important health information through devices and other tools between medical visits could help improve care management and patient outcomes, potentially resulting in increased cost savings. Although many types of PGHD are being used in clinical settings today, the continuous collection and integration of patients' health-data into EHRs to inform clinical care has not been widely achieved across the health care system.

In the 2015 Edition Health IT Certification Criteria final rule (80 FR 62661; 45 CFR 170.315(e)(3), ONC finalized a criterion for patient health information capture functionality within certified health IT that allows a user to identify, record, and access information directly and electronically shared by a patient. We finalized a PGHD measure requiring health care providers to incorporate patient generated health data or data from a nonclinical setting into CEHRT (80 FR 62851). However, we removed this measure in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41663 through 41664), due to concerns that the measure was not fully health IT-based and could include paper-based actions, an approach which did not align with program priorities to advance the use of CEHRT. Stakeholder comments regarding this measure also noted that manual processes to conduct actions associated with the measure could increase health care provider reporting burden and that there was confusion over which types of data would be applicable and the situations in which the patient data would apply (83 FR 41663 through 41664). At the same time, there was ample support from the public for ONC and CMS to continue to advance certified health IT capabilities to capture PGHD.

However, we continue to believe that it is important for the Promoting Interoperability Program to explore new ways to incentivize health care providers who take proactive steps to advance the emerging use of PGHD. As relevant technologies and standards continue to evolve, there may be new program approaches through which we can address challenges related to emerging standards for PGHD capture, appropriate clinical workflows for receiving and reviewing PGHD, and advance the technical architecture needed to support PGHD use.

In 2018, ONC released the white paper ''Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024,'' [830] which describes key challenges, opportunities and enabling actions for different stakeholders, including clinicians, to advance the use of PGHD. For instance, the report identifies an enabling action around supporting ''clinicians to work within and across organizations to incorporate prioritized PGHD use cases into their workflows.'' This action urges clinicians and care teams to identify priority use cases and relevant PGHD types that would be valuable to improving care delivery for patient populations. It also highlights the importance of developing clinical workflows that avoid overwhelming the care team with extraneous data, by encouraging care teams to develop management strategies for shared responsibilities around collecting, verifying, and analyzing PGHD. A second enabling action the white paper identifies for clinicians is ''collaboration between clinicians and

[829] For more information, we refer readers to: *https://www.healthit.gov/topic/scientific-initiatives/patient-generated-health-data.*

[830] *https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf.*

developers to advance technologies supporting PGHD interpretation and use.'' This enabling action highlights feedback for developers about prioritized use cases and application features as critical to ensuring that the necessary refinements are made to technology solutions to effectively support the capture and use of PGHD. Finally, the report encourages ''clinicians in providing patient education to encourage PGHD capture and use in ways that maximize data quality,'' recognizing the important role that clinicians can play in helping patients understand how to share PGHD, the differences between solicited and unsolicited PGHD, and how PGHD are relevant for the patient's care.

Considering the enabling actions for clinicians identified in the white paper, we are interested in ways that the Promoting Interoperability Program could adopt new elements related to PGHD that: (1) Represent clearly defined uses of health IT; (2) are linked to positive outcomes for patients; and (3) advance the capture, use, and sharing of PGHD. In considering how the Promoting Interoperability Program could continue to advance the use of PGHD, we also note that a future program element related to PGHD would not necessarily need to be implemented as a traditional measure requiring reporting of a numerator and denominator. For instance, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20538), we requested comment on the concept of ''health IT'' or ''interoperability'' activities to which a health care provider could attest, potentially in lieu of reporting on measures associated with certain objectives. By addressing the use of PGHD through such a concept, rather than traditional measure reporting, we could potentially reduce the reporting burden associated with a new PGHD-related program element.

We are inviting stakeholder comment on these concepts, and the specific questions below:

- What specific use cases for capture of PGHD as part of treatment and care coordination across clinical conditions and care settings are most promising for improving patient outcomes? For instance, use of PGHD for capturing advanced directives and pre/post-operation instructions in surgery units.
- Should the Promoting Interoperability Program explore ways to include bonus points for health care providers engaging in activities that pilot promising technical solutions or approaches for capturing PGHD and incorporating it into CEHRT using standards-based approaches?
- Should inpatient health care providers be expected to collect information from their patients outside of scheduled appointments or procedures? What are the benefits and concerns about doing so?
- Should the Promoting Interoperability Program explore ways to reward health care providers for implementing best practices associated with optimizing clinical workflows for obtaining, reviewing, and analyzing PGHD?

We believe the bi-directional availability of data, meaning that both patients and their health care providers have real-time access to the patient's electronic health record, is critical. This includes patients being able to import their health data into their medical record and have it be available to health care providers. We welcome input on how we can encourage and enable health care providers to advance capture, exchange, and use of PGHD.

g. Request for Information (RFI) on Engaging in Activities That Promote the Safety of the EHR

The widespread adoption of EHRs has transformed the way health care is delivered, offering improved availability of patient health information, supporting more informed clinical decision making, and reduce medical errors.[831] However, many stakeholders have identified risks to patient safety as one of the unintended consequences that may result from implementation of EHRs. By disrupting established workflows and presenting clinicians with new challenges, EHR implementation may increase the incidence of certain errors, resulting in harm to patients.

As we continue to advance the use of CEHRT in health care, we are seeking comment on how to further mitigate the specific safety risks that may arise from technology implementation. Specifically, we are seeking comment on ways that the Promoting Interoperability Program may reward hospitals for engaging in activities that can help to reduce errors associated with EHR implementation.

For instance, we are requesting comment on a potential future change to the program under which hospitals would receive points towards their Promoting Interoperability Program score for attesting to performance of an assessment based on one of the ONC SAFER Guides. The SAFER Guides (available at: *https://www.healthit.gov/topic/safety/safer-guides*) are designed to help healthcare organizations conduct self-assessments to optimize the safety and safe use of EHRs in nine different areas: High Priority Practices, Organizational Responsibilities, Contingency Planning, System Configuration, System Interfaces, Patient Identification, Computerized Provider Order Entry, Test Results Reporting and Follow-Up, and Clinician Communication.

Each of the SAFER Guides is based on the best evidence available, including a literature review, expert opinion, and field testing at a wide range of healthcare organizations, from small ambulatory practices to large health systems. A number of EHR developers currently utilize the SAFER Guides as part of their health care provider training modules.

Specifically, we might consider offering points towards the Promoting Interoperability Program score to hospitals that attest to conducting an assessment based on the High Priority Practices [832] and/or the Organizational Responsibilities [833] SAFER Guides which cover many foundational concepts from across the guides. Alternatively we might consider awarding points for review of all nine of the SAFER Guides. We are also inviting comments on alternatives to the SAFER Guides, including appropriate assessments related to patient safety, which should also be considered as part of any future bonus option.

We are requesting comment on the ideas above, as well as inviting stakeholders to suggest other approaches we might take to rewarding activities that promote reduction of safety risks associated with EHR implementation as part of the Promoting Interoperability Program.

IX. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2019 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the proposed policies set forth in this proposed rule. MedPAC

[831] *https://www.healthit.gov/topic/health-it-basics/improved-patient-care-using-ehrs.*

[832] *https://www.healthit.gov/sites/default/files/safer/guides/safer_high_priority_practices.pdf.*

[833] *https://www.healthit.gov/sites/default/files/safer/guides/safer_organizational_responsibilities.pdf.*

recommendations for the IPPS for FY 2020 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at: *http://www.medpac.gov.*

X. Other Required Information

A. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Following is a listing of the IPPS-related data files that are available.

Commenters interested in discussing any data files used in construction of this proposed rule should contact Michael Treitel at (410) 786–4552.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, Parts II and III from FY 2016 Medicare cost reports used to create the proposed FY 2020 IPPS wage index. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.L. of the preamble of this proposed rule.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Periods Available: FY 2007 through FY 2020 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the CY 2016 occupational mix survey data to be used to compute the occupational mix adjusted wage indexes. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.L. of the preamble of this proposed rule.

Media: Internet at: *https://www.cms.gov/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Period Available: FY 2020 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-AService-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Period Available: FY 2020 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Periods Available: FY 2005 through FY 2020 IPPS Update.

5. FY 2020 IPPS SSA/FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Federal Information Processing Standards (FIPS), county name, and a list of Core-Based Statistical Areas (CBSAs).

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Acute InpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2020 proposed rule home page or the FY 2020 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2020 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: Internet at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year.html.*

(We note that data are no longer offered on a CD. All of the data collected are now available free for download from the cited website.)

7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicare FeeSvcPmtGen/psf_text.html.*

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number based on the MS–DRGs assigned to the hospital's discharges using the GROUPER version in effect on the date of the discharge. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1985 through FY 2020.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or the fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2020 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related

costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present.html.*

Periods Available: FY 1994 through FY 2020 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR tables are ''Before Outliers Removed'' and the AOR is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2020 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-Based Statistical Area (CBSA). The file supports the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2020 proposed rule home page or the FY 2020 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2020 IPPS Update.

13. Hospital Readmissions Reduction Program Supplemental File

This file contains information on the calculation of the Hospital Readmissions Reduction Program (HRRP) payment adjustment. Variables include the proxy excess readmission ratios for acute myocardial infarction (AMI), pneumonia (PN) and heart failure (HF), coronary obstruction pulmonary disease (COPD), total hip arthroplasty (THA)/total knee arthroplasty (TKA), and coronary artery bypass grafting (CABG) and the proxy readmissions payment adjustment for each provider included in the program. In addition, the file contains information on the number of cases for each of the applicable conditions excluded in the calculation of the readmission payment adjustment factors as well as other information used in the calculation of the annual payment adjustment factors. The file supports the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2020 proposed rule home page or the FY 2020 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2020 IPPS Update.

14. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for FY 2020. Variables include the data used to determine a hospital's share of uncompensated care payments, total uncompensated care payments and estimated per claim uncompensated care payment amounts. The file supports the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2020 proposed rule home page or the FY 2020 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2020 IPPS Update.

15. New Technology Thresholds File

This file contains the cost thresholds by MS–DRG used to evaluate applications for new technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. Two versions of this file are created each year to support rulemaking. (We note that the information in this file was previously provided in Table 10 of the annual IPPS proposed and final rules (83 FR 41739).)

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2019 final rule home page for the FY 2020 application thresholds, or click on the FY 2020 proposed rule home page for the proposed FY 2021 application thresholds or on the FY 2020 final rule home page for the final FY 2021 application thresholds) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Periods Available: For FY 2020 and FY 2021 applications.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for Application for GME Resident Slots

The information collection requirements associated with the preservation of resident cap positions from closed hospitals, addressed in section IV.J.3. of the preamble of this proposed rule are not subject to the Paperwork Reduction Act, as stated in section 5506 of the Affordable Care Act.

3. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. OMB has currently approved 2,520,100 hours of burden and approximately $92.2 million under OMB Control Number 0938–1022, accounting for information collection burden experienced by 3,300 IPPS hospitals and 1,100 non-IPPS hospitals for the FY 2021 payment determination. Below we describe the burden changes with regards to collection of information under OMB Control Number 0938–1022 for IPPS hospitals due to the proposed policies in this proposed rule.

In section VIII.A.5.b. of the preamble of this proposed rule, we are proposing to adopt the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (Hybrid HWR measure) (NQF #2879) in a stepwise approach, beginning with two years of voluntary reporting which would run from July 1, 2021 through June 30, 2022, and from July 1, 2022 through June 30, 2023, before requiring reporting of the measure for the reporting period that would run from July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination and subsequent years. We are also proposing reporting and submission requirements for the Hybrid HWR measure. We expect these proposals will affect our collection of information burden estimates. Details on these proposals, as well as the expected burden changes, are discussed further below.

In section VIII.A. of the preamble of this proposed rule, we also are proposing to: (1) Adopt two opioid-related eCQMs beginning with the CY 2021 reporting period/FY 2023 payment determination: (a) Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e), and (b) Hospital Harm—Opioid-Related Adverse Events eCQM; (2) remove the claims-only version of the Hospital-Wide All-Cause Readmission measure beginning with the FY 2026 payment determination; (3) extend the current eCQM reporting and submission requirements for the CY 2020 reporting period/FY 2022 payment determination and CY 2021 reporting period/FY 2023 payment determination; (4) change the eCQM reporting and submission requirements for the CY 2022 reporting period/FY 2024 payment determination, such that hospitals would be required to report one, self-selected calendar quarter of data for: (a) Three self-selected eCQMs, and (b) the proposed Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e), for a total of four eCQMs; and (5) continue the requirement that EHRs be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. As discussed further below, we do not expect these policies to affect our information collection burden estimates.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38501 through 38504) and FY 2019 IPPS/LTCH PPS final rule (83 FR 41689 through 41694), we estimated that reporting measures for the Hospital IQR Program could be accomplished by staff with a median hourly wage of $18.29 per hour. We note that since then, more recent wage data have become available, and we are updating the wage rate used in these calculations in this proposed rule. The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $18.83 per hour for a Medical Records and Health Information Technician professional.[834] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($18.83 × 2 = $37.66) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will calculate cost burden to hospitals using a wage plus benefits estimate of $37.66 per hour throughout the discussion below for the Hospital IQR Program.

[834] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records and Health Information Technicians. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

b. Information Collection Burden Estimate for the Proposed Adoption of Two eCQMs Beginning With the CY 2021 Reporting Period/FY 2023 Payment Determination

In section VIII.A.5.a. of the preamble of this proposed rule, we are proposing to adopt two opioid-related eCQMs beginning with the CY 2021 reporting period/FY 2023 payment determination:

- Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e); and
- Hospital Harm—Opioid-Related Adverse Events eCQM.

We do not believe that adding two new eCQMs to the measure set will affect the information collection burden of submitting information to CMS under the Hospital IQR Program. As discussed in section VIII.A.10.d.(2) and (3) of the preamble of this proposed rule, we are proposing to extend, for the CYs 2020 and 2021 reporting periods/FYs 2022 and 2023 payment determinations, our current eCQM reporting requirements, which require hospitals to submit one self-selected calendar quarter of data for four self-selected eCQMs each year. These new proposed measures would be added to the eight available eCQMs in the eCQM measure set from which hospitals may choose to report in order to satisfy these requirements.[835] In other words, while these two new proposed measures would be added to the eCQM measure set, hospitals would not be required to report more than a total of four eCQMs as currently required. Therefore, we do not expect adopting these measures will impact our burden estimates. However, we refer readers to section I.K. of Appendix A of this proposed rule for a discussion of the potential costs associated with the implementation of new eCQMs that are not strictly related to information collection burden.

c. Information Collection Burden Estimate for the Proposed Voluntary Reporting Periods and Subsequent Adoption of the Hybrid Hospital-Wide Readmission Measure With Claims and Electronic Health Record Data (Hybrid HWR Measure)

In section VIII.A.5.b. of the preamble of this proposed rule, we are proposing to establish two additional voluntary reporting periods for the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR

[835] We note that in section VIII.A.9.d.(4) of the preamble of this proposed rule we are proposing that, beginning with the CY 2022 reporting period, hospitals must report data on the Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) as one of the four required eCQMs.

measure). The first voluntary reporting period would run from July 1, 2021 through June 30, 2022, and the second would run from July 1, 2022 through June 30, 2023. We also are proposing to require reporting of the Hybrid HWR measure immediately thereafter and for subsequent years, beginning with the reporting period which runs from July 1, 2023 through June 30, 2024 and which would affect the FY 2026 payment determination.

As a hybrid measure, this measure uses both claims-based data and EHR data, specifically, a set of core clinical data elements consisting of vital signs and laboratory test information and patient linking variables collected from hospitals' EHR systems. We do not expect any additional burden to hospitals to report the claims-based portion of this measure, because these data are already reported to the Medicare program for payment purposes.

However, we do expect that hospitals will experience burden in reporting the EHR data. To report the EHR data, as discussed earlier in this proposed rule, we are proposing that hospitals would use the same submission process required for eCQM reporting; specifically, these data would be required to be reported using QRDA I files submitted to the CMS data receiving system, and using EHR technology certified to the 2015 Edition of CEHRT. Accordingly, we expect the burden associated with reporting of this measure to be similar to our estimates for eCQM reporting; that is, 10 minutes per measure, per quarter. Therefore, using the estimate of 10 minutes per measure per quarter (10 minutes × 1 measure × 4 quarters = 40 minutes), we estimate that our proposal will result in a burden increase of 0.67 hours (40 minutes) per hospital per year. Beginning with the first voluntary reporting period, which runs from July 1, 2021 through June 30, 2022, we estimate an annual burden increase of 2,211 hours across participating hospitals (0.67 hours × 3,300 IPPS hospitals). Using the updated wage estimate described above, we estimate this to represent a cost increase of $83,266 ($37.66 hourly wage × 2,211 annual hours) across hospitals. We acknowledge that reporting during the first two years of this proposal is voluntary, but if our proposal to adopt the Hybrid HWR measure is finalized, we will encourage all hospitals to submit data for the Hybrid HWR measure during these voluntary reporting periods. For that reason, our burden estimates are based on the assumption that all hospitals will participate across the two voluntary reporting periods (July 1, 2021 through June 30, 2022, and July 1, 2022 through June 30, 2023), the reporting period in which public reporting begins (July 1, 2023 through June 30, 2024), and subsequent reporting periods.

d. Information Collection Burden Estimate for Proposed Removal of Claims-Only Hospital-Wide All-Cause Readmission Measure (HWR Claims-Only Measure) Beginning With the FY 2026 Payment Determination

In section VIII.A.6. of the preamble of this proposed rule, we are proposing to remove the HWR claims-only measure, beginning with the FY 2026 payment determination when the Hybrid HWR measure begins to be publicly reported. Because the HWR claims-only measure is calculated using data that are already reported to the Medicare program for payment purposes, we do not anticipate that removing this measure would decrease our previously finalized burden estimates.

e. Information Collection Burden Estimates for Proposals Related to eCQM Reporting and Submission Requirements

(1) Information Collection Burden Estimates for Proposed eCQM Reporting and Submission Requirements for the CYs 2020 and 2021 Reporting Periods/FYs 2022 and 2023 Payment Determinations

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41602 through 41607), we finalized eCQM reporting and submission requirements such that hospitals submit one, self-selected calendar quarter of data for four eCQMs in the Hospital IQR Program measure set for the CY 2019 reporting period/FY 2021 payment determination. Our related information collection estimates were discussed at 83 FR 41689 through 41694. In sections VIII.A.10.(d)(2) and (3) of the preamble of this proposed rule, we are proposing to extend the current requirements for two additional years, the CY 2020 reporting period/FY 2022 payment determination and the CY 2021 reporting period/FY 2023 payment determination. We believe there will be no change to the burden estimate due to these proposals because the previous burden estimate of 40 minutes per hospital per year (10 minutes per record × 4 eCQMs × 1 quarter) associated with the eCQM reporting and submission requirements finalized for the CY 2019 reporting period/FY 2021 payment determination would also apply to the CY 2020 reporting period/FY 2022 payment determination and the CY 2021 reporting period/FY 2023 payment determination.

(2) Information Collection Burden Estimate for Proposed eCQM Reporting and Submission Requirements for the CY 2022 Reporting Period/FY 2024 Payment Determination

In section VIII.A.10.d.(4) of the preamble of this proposed rule, for the CY 2022 reporting period/FY 2024 payment determination, we are proposing to change the eCQM reporting and submission requirements, such that hospitals would be required to report one, self-selected calendar quarter of data for: (1) Three self-selected eCQMs, and (2) the proposed Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e), for a total of four eCQMs. We note that the number of calendar quarters of data and total number of eCQMs required would remain the same. We believe there will be no change to the burden estimate because hospitals would still be required to submit one, self-selected calendar quarter of data for a total of four eCQMs in the Hospital IQR Program measure set.

(3) Information Collection Burden Estimate for Proposal To Require That EHRs Be Certified to All Available eCQMs

In section VIII.A.10.d.(5)(B) of the preamble of this proposed rule, we are proposing to continue requiring that EHRs be certified to all available eCQMs in the Hospital IQR Program measure set for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. We do not believe that hospitals will experience an increase in burden associated with this proposal because the use of EHR technology that is certified to all available eCQMs has been required for the Promoting Interoperability Program (83 FR 41672). However, we refer readers to section I.K. of Appendix A of this proposed rule for a discussion of the potential costs associated with this proposal that are not strictly related to information collection burden.

f. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB Control Number 0938–1022, we estimate a total information collection burden increase of 2,211 hours associated with our proposal to adopt the Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) measure and a total cost increase related to this information collection of approximately $83,266 (which also reflects use of an updated hourly wage

rate as discussed above), beginning with the first voluntary reporting period which runs July 1, 2021 through June 30, 2022. These are the total changes to the information collection burden estimates. We will submit the revised information collection estimates to OMB for approval under OMB Control Number 0938–1022.

HOSPITAL IQR PROGRAM FY 2024 PAYMENT DETERMINATION INFORMATION COLLECTION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control No. 0938–1022 for the FY 2024 payment determination							
	Estimated time per record (minutes)	Number reporting quarters per year	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Proposed annual burden (hours) across IPPS hospitals	Previously finalized annual burden (hours) across IPPS hospitals	Net difference in annual burden hours
Hybrid HWR Measure Reporting	10	4	3,300	1	0.67	2,211	N/A	2,211
Total Change in Information Collection Burden Hours: 2,211.								
Total Cost Estimate: Updated Hourly Wage ($37.66) × Change in Burden Hours (2,211) = $83,266.								

4. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

a. Background

As discussed in sections VIII.B. of the preamble of this proposed rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare payment if a PCH does not participate.

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41694 through 41696), the CY 2019 OPPS/ASC final rule with comment period ((83 FR 59149 through 59153), and OMB Control Number 0938–1175 for a detailed discussion of the most recently finalized burden estimates for the program requirements that we have previously adopted. Below we discuss only changes in burden that would result from the proposals in this proposed rule.

In the FY 2018 IPPS/LTCH PPS final rule, we finalized a proposal to utilize the median hourly wage rate, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates going forward (82 FR 38505). The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission for the PCHQR Program. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41695), we utilized a median hourly wage of $18.29 per hour.[836]

We note that since then, more recent wage data have become available, and we are updating the wage rate used in these calculations. The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $18.83 [837] per hour for a Medical Records and Health Information Technician professional. We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 38505). This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($18.83 × 2 = $37.66) to estimate total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs. This approach is consistent with our previously finalized burden calculation methodology (82 FR 38505). Accordingly, we calculate cost burden to PCHs using a wage plus benefits estimate of $37.66 per hour throughout the discussion below.

[836] In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38505), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the PCHQR Program using Bureau of Labor Statistics information.

[837] Occupational Employment and Wages. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

b. Estimated Burden of PCHQR Program Proposals for the FY 2022 Program Year

(1) Proposed Removal of One Web-Based Structural Measure

As discussed in section VIII.B.4. of the preamble of this proposed rule, we are proposing to remove one web-based, structural measure beginning with the FY 2022 program year: External Beam Radiotherapy (EBRT) for Bone Metastases (formerly NQF #1822). As finalized in the FY 2019 IPPS/LTCH PPS final rule, we utilize a time estimate of 15-minutes per measure when assessing web-based and/or structural measures (83 FR 41694). As such, we estimate a reduction of 15 minutes per PCH, and a total annual reduction of approximately 3 hours for all 11 PCHs (.25 hour × 11 PCHs), due to the proposed removal of this measure.

(2) Proposed New Quality Measure Beginning With the FY 2022 Program Year

In section VIII.B.5. of the preamble of this proposed rule, we are proposing to adopt the Surgical Treatment Complications for Localized Prostate Cancer claims-based measure beginning with the FY 2022 program year. Because this measure is claims-based, we do not anticipate any increase in burden on PCHs related to our proposal to adopt this measure, as it does not require facilities to submit any additional data.

c. Summary of Burden Estimates Related to the PCHQR Program Proposals for the FY 2022 Program Year

In summary, if our proposals to remove the External Beam Radiotherapy (EBRT) for Bone Metastases (formerly NQF #1822) measure and to adopt the Surgical Treatment Complications for Localized Prostate Cancer claims-based

measure are finalized as proposed, we estimate an overall burden decrease of approximately 3 hours across all 11 PCHs. Coupled with our estimated salary costs, we estimate that these proposed changes would result in a reduction in annual labor costs of approximately $113 (3 hours × $37.66 hourly labor cost) across the 11 PCHs beginning with the FY 2022 PCHQR Program. Further, the PCHQR Program measure set would consist of 15 measures for the FY 2022 program year. The burden associated with these reporting requirements is currently approved under OMB control number 0938–1175. The information collection will be revised and submitted to OMB.

5. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section IV.H. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, with respect to quality measures, we are proposing to calculate scores for the five NHSN HAI measures used in the Hospital VBP Program using the same data that the HAC Reduction Program uses for purposes of calculating NHSN HAI measure scores under that program, beginning on January 1, 2020 for CY 2020 measure data, which would apply to the Hospital VBP Program starting with data for the FY 2022 program year performance period. Because scores for these measures will be calculated using the same data that we use to calculate scores for the same measures in the HAC Reduction Program, there will be no new data collection burden associated with these measures under the Hospital VBP Program.

6. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section VIII.C. of the preamble of this proposed rule, we are proposing to adopt two Transfer of Health Information quality measures as well as standardized patient assessment data elements (SPADEs) beginning with the FY 2022 LTCH QRP.

We estimate the data elements for the two proposed Transfer of Health Information quality measures will take 1.2 minutes of clinical staff time to report data on discharge. We believe that the additional LTCH CARE Data Set data elements will be completed by registered nurses and licensed vocational nurses. Individual LTCHs determine the staffing resources necessary. We estimate 102,468 discharges from 415 LTCHs annually. This equates to an increase of 2,049 hours in burden for all LTCHs (0.02 hours × 102,468 discharges). Given 0.7 minutes of registered nurse time at $70.72 per hour and 0.5 minutes of licensed vocational nurse time at $43.96 per hour to complete an average of 247 sets of LTCH CARE Data Set assessments per provider per year, we estimated the total cost will be increased by $289.76 per LTCH annually, or $120,252 for all LTCHs annually. This increase in burden will be accounted for in the information collection under OMB control number 0938–1163.

We estimate the proposed SPADEs will take 11.3 minutes of clinical staff time to report data on admission and 10.5 minutes of clinical staff time to report data on discharge, for a total of 21.8 minutes. We believe that the additional LTCH CARE Data Set data elements will be completed by registered nurses and licensed vocational nurses. Individual LTCHs determine the staffing resources necessary. We estimate 102,468 discharges from 415 LTCHs annually. This equates to an increase of 37,195 hours in burden for all LTCHs (0.363 hours × 102,468 discharges). Given 11.6 minutes of registered nurse time at $70.72 per hour and 10.2 minutes of licensed vocational nurse time at $43.96 per hour to complete an average of 247 sets of LTCH CARE Data Set assessments per provider per year, we estimated the total cost will be increased by $5,209.86 per LTCH annually, or $2,162,093 for all LTCHs annually. This increase in burden will be accounted for in the information collection under OMB control number 0938–1163.

Overall, the proposed changes added 11.3 minutes of clinical staff time to report data on admission and 11.7 minutes of clinical staff time to report data on discharge, for a total of 23.0 minutes. As a result, the cost associated with the proposed changes to the LTCH QRP is estimated at $5,499.63 per LTCH annually or $2,282,346 for all LTCHs annually.

7. ICRs Relating to the Hospital-Acquired Condition (HAC) Reduction Program

In section IV.I. of the preamble of this proposed rule, we discuss proposed requirements for the HAC Reduction Program. In this proposed rule, we are not proposing to remove any measures or adopt any new measures into the HAC Reduction Program. The HAC Reduction Program has adopted six measures. We do not believe that the claims-based CMS PSI 90 measure in the HAC Reduction Program creates or reduces any burden for hospitals because it is collected using Medicare FFS claims hospitals are already submitting to the Medicare program for payment purposes. We note the burden associated with collecting and submitting data for the HAI measures (CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI) via the NHSN system is captured under a separate OMB control number, 0920–0666, and therefore will not impact our burden estimates.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), we finalized our policy to validate NHSN HAI measures under the HAC Reduction Program, which will require hospitals to submit validation templates for the NHSN HAI measures beginning with Q3 CY 2020 discharges. We previously estimated that this policy will result in a net neutral shift of 43,200 hours and approximately $1,580,256.00 with no overall net increase in burden to the HAC Reduction Program (83 FR 41151). OMB has currently approved these 43,200 hours of burden and approximately $1.6 million under OMB control number 0938–1352, accounting for information collection requirements experienced by 3,300 IPPS hospitals for FY 2021 program year.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41697), we used an hourly wage estimate of $18.29 per hour to estimate information collection costs.[838] We note that, since then, more recent wage data have become available, and we are updating the wage rate used in these calculations in this proposed rule. The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $18.83 [839] per hour for a Medical Records and Health Information Technician professional. We calculate the cost of overhead, including fringe benefits, at 100 percent of the hourly wage estimate, as has been done under the Hospital IQR Program in the previous years (82 FR 38504 through 38505; 83 FR 41689 through 41690). This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($18.83 × 2 = $37.66) to estimate total cost is a

[838] In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41697), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the HAC Reduction Program using Bureau of Labor Statistics information.

[839] Occupational Employment and Wages. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $37.66 per hour.

We estimate a reporting burden of 80 hours (20 hours per record × 1 record per hospital per quarter × 4 quarters) per hospital selected for validation per year to submit the CLABSI and CAUTI templates, and 64 hours (16 hours per record × 1 record per hospital per quarter × 4 quarters) per hospital selected for validation per year to submit the MRSA and CDI templates. We estimate a total burden shift of 43,200 hours ([80 hours per hospital to submit CLABSI and CAUTI templates + 64 hours per hospital to submit MRSA and CDI templates] × 300 hospitals selected for validation) and approximately $1,626,912.00 (43,200 hours × $37.66 per hour[840]) as a result of our policy to validate NHSN HAI data under the HAC Reduction Program. A non-substantive information collection request will be submitted to OMB under control number 0938–1352 to account for the updated costs.

8. ICRs Relating to the Hospital Readmissions Reduction Program

In section IV.G. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital Readmissions Reduction Program. In this proposed rule, we are not proposing to adopt any new measures into the Hospital Readmissions Reduction Program. All six of the Hospital Readmissions Reduction Program's measures are claims-based measures. We do not believe that continuing to use these claims-based measures creates or reduces any burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes.

9. ICRs for the Promoting Interoperability Programs

a. Background

In section VIII.D. of the preamble of this proposed rule, we discuss proposed requirements for the Promoting Interoperability Programs. OMB has currently approved 623,562.19 total burden hours and approximately $61 million under OMB control number 0938–1278, accounting for information collection burden experienced by approximately 3,300 eligible hospitals and CAHs (Medicare-only and dual-eligible) that attest to CMS under the Medicare Promoting Interoperability Program. The collection of information burden analysis below will focus on eligible hospitals and CAHs that attest to the objectives and measures, and report CQMs, under the Medicare Promoting Interoperability Program for the reporting period in CY 2020.

b. Summary of Proposals for Eligible Hospitals and CAHs That Attest to CMS Under the Medicare Promoting Interoperability Program for CY 2020

In section VIII.D.3.b. of the preamble of this proposed rule, we are proposing to change the reporting requirement for the Query of Prescription Drug Monitoring Program (PDMP) measure from numerator and denominator to a ''yes/no'' response beginning with CY 2019 for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program. We expect this proposal to affect our collection of information burden estimates for CY 2019 and CY 2020.

This proposed rule also includes the following proposals for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program, which we do not expect to affect our collection of information burden estimates for CY 2020: (1) Eliminate the requirement that, for the FY 2020 payment adjustment year, for an eligible hospital that has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period in CY 2019 must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2019 deadline; (2) establish an EHR reporting period of a minimum of any continuous 90-day period in CY 2021 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program attesting to CMS; (3) require that the Medicare Promoting Interoperability Program measure actions must occur within the EHR reporting period beginning with the EHR reporting period in CY 2020; (4) revise the Query of PDMP measure to make it an optional measure worth five bonus points in CY 2020, remove the exclusions associated with this measure in CY 2020, and clearly state our intended policy that the measure is worth a full 5 bonus points in CY 2019 and CY 2020; (5) change the maximum points available for the e-Prescribing measure to 10 points beginning in CY 2020, in the event we finalize the proposed changes to the Query of PDMP measure; (6) remove the Verify Opioid Treatment Agreement measure beginning in CY 2020 and clearly state our intended policy that the measure is worth a full 5 bonus points in CY 2019; and (7) revise the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to more clearly capture the previously established policy regarding CHERT use. We also are proposing to amend our regulations to incorporate several of these proposals.

Although we are proposing to remove the Verify Opioid Treatment Agreement measure, we do not anticipate a change of burden for the Electronic Prescribing objective that this measure is associated with. In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62917), we estimated it would take an individual provider or designee approximately 10 minutes to attest to each objective and associated measure that requires a numerator and denominator to be generated. For objectives and associated measures requiring a numerator and denominator, we limit our estimates to actions taken in the presence of certified EHR technology. We do not anticipate a provider will maintain two recordkeeping systems when certified EHR technology is present. Therefore, we assume that all patient records that will be counted in the denominator will be kept using certified EHR technology. In addition, our estimates, provided in Table 21—Burden Estimates Stage 3—495.24 of the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62918 through 62922), are calculated at the objective level, not for each individual measure being reported. We relied on this approach to create our burden estimates and determined that removing the Verify Opioid Treatment Agreement measure would not change burden since eligible hospitals and CAHs would still have to calculate a numerator and denominator for the e-Prescribing measure, which is associated with the Electronic Prescribing objective.

We anticipate that the burden will decrease for the Electronic Prescribing objective due to the proposal to require a ''yes/no'' response instead of a numerator/denominator manual calculation for the Query of PDMP measure. The current numerator/denominator response for the Query of PDMP measure may require an eligible hospital or CAH to manually calculate the numerators and denominators

[840] Occupational Employment and Wages. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

outside of the certified EHR technology. The burden that was calculated for the Electronic Prescribing objective included the numerator/denominator calculated by the certified EHR technology, which is 10 minutes per respondent, plus the calculations performed manually outside of the certified EHR technology for the Query of PDMP measure, which we estimated at 40 minutes per respondent. We estimated that all eligible hospitals and CAHs would take 40 minutes per respondent to complete this measure by using the data found in certified EHR technology and manually tracking the number of times that they query the PDMP outside of certified EHR technology. This is a reduction in total burden of 40 minutes per respondent from FY 2019 IPPS/LTCH PPS final rule (83 FR 41698) reporting estimates which we estimate a total burden estimate of 7 hours and 10.8 minutes per respondent. With the proposed reporting requirement change for the Query of PDMP measure from a numerator and denominator to a ''yes/no'' response beginning CY 2019, the certified EHR technology would be able to capture all of the actions required for the measures associated with the Electronic Prescribing objective; as a result, we estimate 10 minutes per respondent for this objective.

In section VIII.D.6. of the preamble of this proposed rule, we are making a number of proposals with respect to the reporting of CQM data, including proposing to add two opioid-related measures beginning with the reporting period in CY 2021 and proposing the reporting period, reporting criteria, submission period, and form and method requirements for CQM reporting in CY 2020. However, for the reporting period in CY 2020, these proposals are continuations of current policies and therefore we do not believe that there would be a change in burden for CY 2020.

c. Information Collection Burden Estimates for the Proposed Update to the Query of PDMP Measure

In section VIII.D.3.b. of the preamble of this proposed rule, we are proposing to change the Query of PDMP measure's reporting requirement from a numerator and denominator to a ''yes/no'' response beginning in CY 2019. We stated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41652) that we acknowledge that due to the varying integration of PDMPs into EHR systems, additional time, workflow changes and manual data capture and calculation would be needed to complete the query. This would result in some eligible hospitals and CAHs having to manually calculate the numerator and denominator for the Query of PDMP measure. We estimated that the action for eligible hospitals and CAHs to manually capture this measure would be a total of 40 minutes respectively for CY 2019 and CY 2020. By proposing to reduce the Query of PDMP measure reporting requirement from a numerator and denominator to a ''yes/no'' response, manual calculation would not be required by eligible hospitals and CAHs. We estimate that the change in reporting requirement for the Query of PDMP measure would result in a reduction of collection of information burden of 2,200 hours for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program for CY 2020. The total saving for CY 2019 and CY 2020 is 4,400 collection of information burden hours.

Proposal	Estimated time for reporting CY 2019	Total time (+/− hours) for CY 2019	Estimated time for reporting CY 2020	Total time (+/− hours) for CY 2020	Total time (+/− hours) for CYs 2019 and 2020
Change reporting requirement for the Query of PDMP measure.	3300 eligible hospitals and CAHs × 40 minutes.	−132,000 minutes or −2,200 hours.	3300 eligible hospitals and CAHs × 47 minutes.	−132,100 minutes or −2,200 hours.	−264,000 minutes or −4,400 hours.

d. Summary of Collection of Information Burden Estimates

1. Summary of Estimates Used To Calculate the Collection of Information Burden

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62917), we estimated it would take an individual provider or designee approximately 10 minutes to attest to each objective and associated measure that requires a numerator and denominator to be generated. The measures that require a ''yes/no'' response would take approximately one minute to complete. We estimated that the Security Risk Analysis measure would take approximately 6 hours for an individual provider or designee to complete (we note this measure is still part of the program, but is not subject to performance-based scoring). We continue to believe these are appropriate burden estimates for reporting and have used this methodology in our proposed collection of information burden estimates for this proposed rule.

Given the proposals in this proposed rule, we estimate a total burden estimate of 6 hours 31 minutes per respondent. This is a reduction in total burden of 40 minutes per respondent from FY 2019 IPPS/LTCH PPS final rule (83 FR 41698) reporting estimates which we estimate a total burden estimate of 7 hours and 10.8 minutes per respondent. This represents a reduction of 2,200 total reporting hours (40 minutes * 3300 respondents = 2,200 hours) for the Medicare Promoting Interoperability Program.

MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN PER RESPONDENT FOR CY 2020: § 495.24(e)—OBJECTIVES/MEASURES MEDICARE

[Eligible hospitals/CAHs]

Objective	Measure	Burden estimate per eligible hospital and CAH
N/A	Security Risk Analysis	6 hours.

MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN PER RESPONDENT FOR CY 2020: § 495.24(e)—OBJECTIVES/MEASURES MEDICARE—Continued

[Eligible hospitals/CAHs]

Objective	Measure	Burden estimate per eligible hospital and CAH
Electronic Prescribing	e-Prescribing measure Query of PDMP.	10 minutes.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information Support Electronic Referral Loops by Receiving and Incorporating Health.	10 minutes.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	10 minutes.
Public Health and Clinical Data Exchange.	• Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry—Reporting • Electronic Reportable Laboratory Result Reporting	1 minute.
Total Burden Estimate per Respondent.		6 hours 31 minutes (6.52 hours).

2. Hourly Labor Costs

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62917), we estimated a mean hourly rate of $63.46 for the staff involved in attesting to EHR technology, meaningful use objectives and associated measures, and electronically submitting the clinical quality measures. We also used the mean hourly rate of $67.25 for the staff involved in attesting the objectives and measures under § 495.24(e) in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41698). Based on more recent 2017 data from the Bureau of Labor Statistics (BLS), we are proposing to update this rate to $68.22 per hour for CY 2020.[841]

Based on the number of respondents for the Medicare Promoting Interoperability Program, the estimated burden response per respondent and the hourly labor cost of reporting, we estimate a total cost of $1,442,512.50 for CY 2019 and $1,463,319 for CY 2020.

MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN (TOTAL COST) FOR CY 2019

Regulations section	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total cost ($)
§ 495.24(e)	3,300	3,300	6.5	21,494	$67.25	1,442,512.50

MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN (TOTAL COST) FOR CY 2020

Regulations section	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total cost ($)
§ 495.24(e)	3,300	3,300	6.5	21,494	68.22	1,463,319

This estimate takes into account the reduction of 2,200 total reporting hours per CY and the finalized hourly labor cost for CY 2019 and the proposed updated hourly labor cost for CY 2020. This estimate represents a cost reduction of $150,909.00 ($1,593,421.50 − $1,442,512.50) for the CY 2019 and $130,102.50 ($1,593,421.50 − $1,463,319) for the CY 2020 when comparing to the total cost from the FY 2019 IPPS/LTCH PPS final rule (83 FR 41698) estimates.

10. ICRs for New Technology Add-On Payments

Section II.H. of the preamble of this proposed rule discusses new technology add-on payments. Applicants for these add-on payments must submit a formal request that includes information used to demonstrate that the medical service or technology meets the new technology add-on payment criteria. The burden associated with this application process is the time and effort necessary for an applicant to complete and submit the application and associated supporting information. The burden associated with this requirement is subject to the PRA, and is currently approved under OMB control number 0938–1347.

Section II.H.8. of the preamble of this proposed rule discusses a proposed alternative inpatient new technology

[841] *https://www.bls.gov/oes/2017/may/oes231011.htm.*

add-on payment pathway for transformative new devices. The burden associated with the changes that would be needed to the new technology add-on payment application process if this proposal is finalized will be discussed in a forthcoming revision of the information collection requirement (ICR) request currently approved under OMB control number 0938–1347. The revised ICR request is currently under development. However, upon completion of the revised ICR request, we will detail the proposed revisions of the ICR and publish the required 60-day and 30-day notices to solicit public comments in accordance with the requirements of the PRA.

11. Summary of All Burden in This Proposed Rule

Below is a chart reflecting the total burden and associated costs for the provisions included in this proposed rule.

Information collection requests	Burden hours increase/decrease (+/−)*	Cost (+/−)*
Application for GME Resident Slots	N/A	N/A
Hospital Inpatient Quality Reporting Program	+2,211	+$83,266
Hospital Value-Based Purchasing Program[1]	N/A	N/A
HAC Reduction Program	N/A	N/A
Hospital Readmissions Reduction Program[2]	N/A	N/A
Promoting Interoperability Programs	−2,200	−$130,102
LTCH Quality Reporting Program	+39,244	+$2,282,346
PPS-Exempt Cancer Hospital Quality Reporting Program	−3	−$113
Total	+39,252	+$2,235,397

* Numbers rounded.

[1] Because the FY 2022 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare fee-for-service claims data that hospitals are already submitting to CMS for payment purposes, the program does not anticipate any change in burden associated with this proposed rule.

[2] Because the Hospital Readmissions Reduction Program measures are all collected via Medicare fee-for-service claims that hospitals are already submitting to CMS for payment purposes, there is no unique information collection burden associated with the program.

C. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XI. Provider Reimbursement Review Board Appeals

The Provider Reimbursement Review Board (PRRB) was established in 1972 to handle Medicare Part A provider cost reimbursement appeals. Congress' intent with the creation of the PRRB was to provide an administrative appeals forum for Medicare payment disputes, and an opportunity for providers who are dissatisfied with the reimbursement determination made by their Medicare contractor or CMS to request and be afforded a hearing to adjudicate the issues involved.

Between 2015 and 2017, Medicare Part A providers filed cost report appeals at a higher rate than were resolved. On average, 3,000 appeals were filed per year and approximately 2,200 were resolved. The appeals inventory is now over 10,000 (including approximately 5,000 group appeals). The resolution process can take an average of 4 years, excluding cases in district court. CMS, providers, and MACs must expend considerable time and resources preparing and processing appeals.

As part of CMS' ongoing efforts to reduce provider burden, we are examining the growing inventory of PRRB appeals. To date, we have identified certain action initiatives that could be implemented with the goal to: Decrease the number of appeals submitted; decrease the number of appeals in inventory; reduce the time to resolution; and increase customer satisfaction. Some examples of these initiatives are as follows:

- Develop standard formats and more structured data for submitting cost reports and supplemental and supporting documentation.
- Create more clear standards for documentation to be used in auditing of cost reports.
- Enhance the Medicare Cost Report Electronic Filing (MCReF) portal by creating more automation for letter notifications, increasing provider transparency during the cost report reconciliation process, and improving the ability for providers to see where they are in the process.
- Explore opportunities to improve the process for claiming DSH Medicaid eligible days as part of the annual Medicare cost report submission and settlement process.
- Utilize artificial intelligence (AI) design risk protocols based on historical audit outcomes and empirical data to drive the audit and desk review processes.
- Triage the current appeals inventory and expand the provider's utilization of PRRB rules 46 and 47.2.3 (that is, resolve appeal issues through the cost report reopening process).

As part of this effort, in section IV.F.5. of the preamble of this proposed rule, we are requesting public comments on PRRB appeals related to a hospital's Medicaid fraction in the DSH payment adjustment calculation.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services is proposing to amend 42 CFR Chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.64 is amended by adding paragraph (d)(1)(viii) to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(viii) For fiscal year 2020 and subsequent fiscal years, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (3) of this section, less a multifactor productivity adjustment (as determined by CMS).

* * * * *

■ 3. Section 412.87 is amended by—

■ a. Redesignating paragraph (c) as paragraph (d);

■ b. Adding a new paragraph (c); and

■ c. Revising newly redesignated paragraph (d).

The addition and revision read as follows:

§ 412.87 Additional payment for new medical services and technologies: General provisions.

* * * * *

(c) *Eligibility criteria for alternative pathway for certain transformative new devices.* For discharges occurring on or after October 1, 2020, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical devices, if the following conditions are met:

(1) A new medical device has received Food and Drug Administration (FDA) marketing authorization and is part of the FDA's Breakthrough Devices Program.

(2) A medical device that meets the condition in paragraph (c)(1) of this section will be considered new for not less than 2 years and not more than 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Social Security Act) assigned to the new technology (depending on when a new code is assigned and data on the new technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical technology, the medical technology will no longer be considered ''new'' under the criterion of this section.

(3) The new medical device meets the conditions described in paragraph (b)(3) of this section.

(d) *Announcement of determinations and deadline for consideration of new medical service or technology applications.* CMS will consider whether a new medical service or technology meets the eligibility criteria specified in paragraph (b) or paragraph (c) of this section and announce the results in the **Federal Register** as part of its annual updates and changes to the IPPS. CMS will only consider any particular new medical service or technology for add-on payments under paragraph (b) or paragraph (c) of this section, and not both. In addition, CMS will only consider, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA approval or clearance by July 1 prior to the particular fiscal year.

■ 4. Section 412.88 is amended by revising paragraphs (a)(2) and (b) to read as follows:

§ 412.88 Additional payment for new medical service or technology.

(a) * * *

(2)(i) *For discharges occurring before October 1, 2019.* If the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(A) 50 percent of the costs of the new medical service or technology; or

(B) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

(ii) *For discharges occurring on or after October 1, 2019.* If the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(A) 65 percent of the costs of the new medical service or technology; or

(B) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

(b)(1) *For discharges occurring before October 1, 2019.* Unless a discharge case qualifies for outlier payment under § 412.84, Medicare will not pay any additional amount beyond the DRG payment plus 50 percent of the estimated costs of the new medical service or technology.

(2) *For discharges occurring on or after October 1, 2019.* Unless a discharge case qualifies for outlier payment under § 412.84, Medicare will not pay any additional amount beyond the DRG payment plus 65 percent of the estimated costs of the new medical service or technology.

■ 5. Section 412.101 is amended by revising paragraph (e) to read as follows:

§ 412.101 Special treatment: Inpatient hospital payment adjustment for low-volume hospitals.

* * * * *

(e) *Special treatment regarding hospitals operated by the Indian Health Service (IHS) or a Tribe.* (1) For discharges occurring in FY 2018 and subsequent fiscal years—

(i) A hospital operated by the IHS or a Tribe will be considered to meet the applicable mileage criterion specified under paragraph (b)(2) of this section if it is located more than the specified number of road miles from the nearest subsection (d) hospital operated by the IHS or a Tribe.

(ii) A hospital, other than a hospital operated by the IHS or a Tribe, will be considered to meet the applicable mileage criterion specified under paragraph (b)(2) of this section if it is located more than the specified number of road miles from the nearest subsection (d) hospital other than a subsection (d) hospital operated by the IHS or a Tribe.

(2) Subject to the requirements set forth in § 405.1885 of this chapter, a hospital may request the application of the policy described in paragraph (e)(1) of this section for discharges occurring in FY 2011 through FY 2017.

■ 6. Section 412.103 is amended by—

■ a. Revising paragraph (b)(3);

■ b. Adding paragraph (g)(1)(iii);

■ c. Revising paragraph (g)(2)(iii); and

■ d. Adding paragraphs (g)(3) and (4).

The revisions and additions read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

* * * * *

(b) * * *

(3) *Submission of application.* An application may be submitted to the CMS Regional Office by the requesting hospital by mail or by facsimile or other electronic means.

* * * * *

(g) * * *

(1) * * *

(iii) The provisions of paragraphs (g)(1)(i) and (ii) of this section are effective for all written requests submitted by hospitals before October 1, 2019 to cancel rural reclassifications.

(2) * * *

(iii) The provisions of paragraphs (g)(2)(i) and (ii) of this section are effective for all written requests submitted by hospitals on or after October 1, 2007 and before October 1, 2019, to cancel rural reclassifications.

(3) *Cancellation of rural reclassification on or after October 1, 2019.* For all written requests submitted by hospitals on or after October, 1, 2019 to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of a Federal fiscal year. The hospital's cancellation of the classification is effective beginning with the next Federal fiscal year.

(4) *Special rule for hospitals that opt to receive county out-migration adjustment.* A rural reclassification will be considered canceled effective for the next Federal fiscal year when a hospital, by submitting a request to CMS within 45 days of the date of public display of the proposed rule for the next Federal fiscal year at the Office of the Federal Register, opts to accept and receives its county out-migration wage index adjustment determined under section 1886(d)(13) of the Act in lieu of its geographic reclassification described under section 1886(d)(8)(B) of the Act.

■ 7. Section 412.106 is amended by adding paragraph (g)(1)(iii)(C)(*6*) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C) * * *

(*6*) For fiscal year 2020, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from 2015 cost reports from the most recent HCRIS database extract, except that, for Puerto Rico hospitals and Indian Health Service or Tribal hospitals, CMS will base its estimates on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available year of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data);

* * * * *

■ 8. Section 412.152 is amended by revising the definitions of ''Aggregate payments for excess readmissions'', ''Applicable condition'', ''Base operating DRG payment amount'', and ''Dual-eligible'' to read as follows:

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

* * * * *

Aggregate payments for excess readmissions is, for a hospital for the applicable period, the sum, for the applicable conditions, of the product for each applicable condition of:

(1) The base operating DRG payment amount for the hospital for the applicable period for such condition or procedure;

(2) The number of admissions for such condition or procedure for the hospital for the applicable period;

(3) The excess readmission ratio for the hospital for the applicable period minus the peer-group median excess readmission ratio (ERR); and

(4) The neutrality modifier, a multiplicative factor that equates total Medicare savings under the current stratified methodology to the previous non-stratified methodology.

Applicable condition is a condition or procedure selected by the Secretary—

(1) Among the conditions and procedures for which—

(i) Readmissions represent conditions or procedures that are high volume or high expenditures; and

(ii) Measures of such readmissions have been endorsed by the entity with a contract under section 1890(a) of the Act and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital); or

(2) Among other conditions and procedures as determined appropriate by the Secretary. In expanding the applicable conditions, the Secretary will seek endorsement of the entity with a contract under section 1890(a) of the Act, but may apply such measures without such an endorsement in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

* * * * *

Base operating DRG payment amount is the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount is determined without regard to any payment adjustments under the Hospital Value-Based Purchasing Program, as specified under § 412.162. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, and a low volume of discharges under § 412.101. With respect to a sole community hospital that receives payments under § 412.92(d) or a Medicare-dependent, small rural hospital that receives payments under § 412.108(c), this amount also includes the difference between the hospital-specific payment rate and the Federal payment rate determined under subpart D of this part. With respect to a hospital that is paid under section 1814(b)(3) of the Act, this amount is an amount equal to the wage-adjusted DRG payment amount plus new technology payments that would be paid to such hospitals, absent the provisions of section 1814(b)(3) of the Act.

Dual-eligible. (1) For payment adjustment factor calculations prior to the FY 2021 program year, is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in the State Medicare Authorization Act (MMA) files for the month the beneficiary was discharged from the hospital; and

(2) For payment adjustment factor calculations beginning in the FY 2021 program year, is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in data sourced from the State MMA files for the month the beneficiary was discharged from the hospital, except for those patient beneficiaries who die in the month of discharge, which will be identified using the previous month's data as sourced from the State MMA files.

* * * * *

■ 9. Section 412.154 is amended by redesignating paragraph (e)(4) as paragraph (e)(6) and adding paragraphs (e)(4) and (5) to read as follows:

§ 412.154 Payment adjustments under the Hospital Readmissions Reduction Program.

* * * * *

(e) * * *

(4) The neutrality modifier.

(5) The proportion of dual-eligibles.

* * * * *

■ 10. Section 412.172 is amended by revising paragraphs (f)(2) and (4) to read as follows:

§ 412.172 Payment adjustments under the Hospital-Acquired Condition Reduction Program.

* * * * *

(f) * * *

(2) Hospitals will have a period of 30 days after the receipt of the information provided under paragraph (f)(1) of this section to review and submit corrections for the hospital-acquired condition program scores for each condition that is used to calculate the total hospital-acquired condition score for the fiscal year.

* * * * *

(4) CMS will post the total hospital-acquired condition score and the score on each measure for each hospital on the Hospital Compare website.

* * * * *

■ 11. Section 412.230 is amended by revising paragraph (a)(4) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

(a) * * *

(4) *Application of criteria.* In applying the numeric criteria contained in paragraphs (b)(1) and (2) and (d)(1)(iii) and (iv) of this section, rounding of numbers to meet the mileage or qualifying percentage standards is not permitted.

* * * * *

■ 12. Section 412.256 is amended by revising paragraph (a)(1) to read as follows:

§ 412.256 Application requirements.

(a) * * *

(1) An application must be submitted to the MGCRB according to the method prescribed by the MGCRB.

* * * * *

■ 13. Section 412.522 is amended by adding paragraphs (d)(3) through (6) to read as follows:

§ 412.522 Application of site neutral payment rate.

* * * * *

(d) * * *

(3) For cost reporting periods beginning on or after October 1, 2019, if a long-term care hospital's discharge payment percentage for the cost reporting period is not at least 50 percent, discharges in all cost reporting periods beginning after the notification described under paragraph (d)(2) of this section will be paid under the payment adjustment described in paragraph (d)(4) of this section until reinstated under paragraph (d)(5) or (6) of this section.

(4) For cost reporting periods subject to the payment adjustment under paragraph (d)(3) of this section, the payment for all discharges consists of—

(i) An amount comparable to the hospital inpatient prospective payment system amount as determined under § 412.529(d)(4)(i)(A) and (d)(4)(ii); and

(ii) If applicable, an additional payment for high cost outlier cases based on the fixed-loss amount established for the hospital inpatient prospective payment system in effect at the time of the LTCH discharge.

(5) For full reinstatement—

(i) When the discharge payment percentage for a cost reporting period is at least 50 percent, the payment adjustment described in paragraph (d)(4) of this section will be discontinued for cost reporting periods beginning on or after the notification described under paragraph (d)(2) of this section.

(ii) A long-term care hospital reinstated under paragraph (d)(5)(i) of this section will be subject to the payment adjustment under paragraph (d)(4) of this section if, after being reinstated, it again meets the criteria in paragraph (d)(3) of this section.

(6) For special probationary reinstatement—

(i) A hospital that would be subject to the payment adjustment under paragraph (d)(4) of this section for a cost reporting period will have the payment adjustment delayed for that period if, for the period of at least 5 consecutive months of the immediately preceding 6-month period, the discharge payment percentage is at least 50 percent.

(ii) For any cost reporting period for which the payment adjustment under paragraph (d)(4) of this section was delayed under paragraph (d)(6)(i) of this section, the payment adjustment under paragraph (d)(4) of this section will be applied if the discharge payment percentage for such cost reporting period is not at least 50 percent.

■ 14. Section 412.523 is amended by adding paragraph (c)(3)(xvi) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rate.

* * * * *

(c) * * *

(3) * * *

(xvi) *For long-term care prospective payment system fiscal year beginning October 1, 2019, and ending September 30, 2020.* The long-term care hospital prospective payment system standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2019 and ending September 30, 2020 is the standard Federal payment rate for the previous long-term care prospective payment system fiscal year updated by 2.7 percent and further adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

■ 15. Section 412.560 is amended by revising paragraphs (d)(1) and (3) and (f)(1) to read as follows:

§ 412.560 Requirements under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP).

* * * * *

(d) * * *

(1) *Written letter of non-compliance decision.* Long-term care hospitals that do not meet the requirement in paragraph (b) of this section for a program year will receive a notification of non-compliance sent through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the MAC.

* * * * *

(3) *CMS decision on reconsideration request.* CMS will notify long-term care hospitals, in writing, of its final decision regarding any reconsideration request through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the MAC.

* * * * *

(f) * * *

(1) Long-term care hospitals must meet or exceed two separate data completeness thresholds: One threshold set at 80 percent for completion of measures data and standardized patient assessment data collected using the LTCH CARE Data Set submitted through the CMS designated data submission system; and a second threshold set at 100 percent for measures data collected and submitted using the CDC NHSN.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 16. The authority for part 413 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 17. Section 413.70 is amended by revising paragraph (b)(5)(i)(C) and adding paragraph (b)(5)(i)(D) to read as follows:

§ 413.70 Payment for services of a CAH.

* * * * *

(b) * * *

(5) * * *

(i) * * *

(C) Effective for cost reporting periods beginning on or after October 1, 2011 and on or before September 30, 2019, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. If there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH. (D) Effective for cost reporting periods beginning on or after October 1, 2019, payment for ambulance services furnished by a CAH or by a CAH-owned and operated entity is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. If there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 18. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 19. Section 495.4 is amended—

■ a. In the definition of ''EHR reporting period'', by adding paragraph (2)(v); and

■ b. In the definition of ''EHR reporting period for a payment adjustment year'', by revising paragraph (2)(iii)(A) and adding paragraphs (2)(v) and (3)(v).

The additions and revision read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period. * * *

(2) * * *

(v) For the FY 2021 payment year as follows: Under the Medicare Promoting Interoperability Program, for a Puerto Rico eligible hospital, any continuous 90-day period within CY 2021.

EHR reporting period for a payment adjustment year. * * *

(2) * * *

(iii) * * *

(A) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2019 and applies for the FY 2020 and FY 2021 payment adjustment years.

* * * * *

(v) The following are applicable for 2021:

(A) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2021 and applies for the FY 2022 and 2023 payment adjustment years. For the FY 2022 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2021.

(B) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2021 and applies for the FY 2023 payment adjustment year.

(3) * * *

(v) The following are applicable for 2021:

(A) If a CAH has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2021 and applies for the FY 2021 payment adjustment year.

(B) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2021 and applies for the FY 2021 payment adjustment year.

* * * * *

■ 20. Section 495.24 is amended by revising paragraphs (e)(1), (e)(4)(iii), (e)(5)(ii)(B), (e)(5)(iii) through (v), and (e)(6)(ii)(B) to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * * *

(e) * * *

(1) *General rule.* (i) Except as specified in paragraph (e)(2) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 3 criteria specified in this paragraph (e) and earn a total score of at least 50 points to meet the definition of a meaningful EHR user.

(ii) Beginning in CY 2020, the numerator and denominator of measures increment based on actions occurring during the EHR reporting period selected by the eligible hospital or CAH, unless otherwise indicated.

* * * * *

(4) * * *

(iii) *Security risk analysis measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.

(5) * * *

(ii) * * *

(B) In 2020 and subsequent years, eligible hospitals and CAHs must meet the e-Prescribing measure in paragraph (e)(5)(iii)(A) of this section and have the option to report on the query of PDMP measure in paragraph (e)(5)(iii)(B) of this section. In 2020 and subsequent years, the electronic prescribing objective in paragraph (e)(5)(i) of this section is worth up to 15 points.

(iii) *Measures*—(A) *e-Prescribing measure.* Subject to paragraph (e)(3) of this section, at least one hospital discharge medication order for permissible prescriptions (for new and changed prescriptions) is queried for a drug formulary and transmitted electronically using CEHRT. This measure is worth up to 10 points in CY 2019 and subsequent years.

(B) *Query of prescription drug monitoring program (PDMP) measure.* Subject to paragraph (e)(3) of this section, for at least one Schedule II

opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law. This measure is worth 5 bonus points in CY 2019 and CY 2020.

(C) *Verify opioid treatment agreement measure.* Subject to paragraph (e)(3) of this section, for at least one unique patient for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the eligible hospital or CAH seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient's electronic health record using CEHRT. This measure is worth 5 bonus points in CY 2019.

(iv) *Exclusions in accordance with paragraph (e)(2) of this section and redistribution of points.* An exclusion claimed under paragraph (e)(5)(v) of this section will redistribute 10 points in CY 2019 and CY 2020 equally among the measures associated with the health information exchange objective under paragraph (e)(6) of this section.

(v) *Exclusion in accordance with paragraph (e)(2) of this section.* Beginning with the EHR reporting period in CY 2019, any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the eligible hospital or CAH's EHR reporting period may be excluded from the measure specified in paragraph (e)(5)(iii)(A) of this section.

(6) * * *

(ii) * * *

(B) *Support electronic referral loops by receiving and incorporating health information measure:* Subject to paragraph (e)(3) of this section, for at least one electronic summary of care record received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list using CEHRT.

* * * * *

Dated: March 26, 2019.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: April 2, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendices will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2019, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2019

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2020 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2020. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that will be effective for cost reporting periods beginning on or after October 1, 2019.

In addition, we are setting forth a description of the methods and data we used to determine the proposed LTCH PPS standard Federal payment rate that would be applicable to Medicare LTCHs for FY 2020.

In general, except for SCHs and MDHs, for FY 2020, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (including, as discussed in section IV.G. of the preamble of this proposed rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor. Section 50205 of the Bipartisan Budget Act of 2018 extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.

As discussed in section IV.B. of the preamble of this proposed rule, in accordance with section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), for FY 2020, subsection (d) Puerto Rico hospitals will continue to be paid based on 100 percent of the national standardized amount. Because Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update, our discussion below does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare

inpatient operating costs for acute care hospitals for FY 2020. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2020. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2020. In section V. of this Addendum, we discuss proposed policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2020. The tables to which we refer to in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2020

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. Below we discuss the factors we are proposing to use for determining the proposed prospective payment rates for FY 2020.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2020, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section IV.B. of the preamble of this proposed rule for a complete discussion on the proposed FY 2020 inpatient hospital update. Below is a table with these four scenarios:

PROPOSED FY 2020 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2020	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase	3.2	3.2	3.2	3.2
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	−0.8	−0.8
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	−2.4	0	−2.4
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.5	−0.5	−0.5	−0.5
Proposed Applicable Percentage Increase Applied to Standardized Amount	2.7	0.3	1.9	−0.5

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2020.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2019 budget neutrality factor and applying a revised factor.
- A positive adjustment of 0.5 percent in FYs 2019 through 2023 as required under section 414 of the MACRA.
- An adjustment to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. This demonstration program is required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years, as amended by section 15003 of Public Law 114–255

which amended section 410A of Public Law 108–173 to provide for a 10-year extension of the demonstration program (in place of the 5-year extension required by the Affordable Care Act) beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173.

- An adjustment to the standardized amount (using our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act) to implement in a budget neutral manner our proposed transition (described in section III.N.3.d. of the preamble of this proposed rule) for hospitals negatively impacted due to proposed changes to the wage index. We refer readers to section III.N. of the preamble of this proposed rule for a detailed discussion.
- An adjustment to remove the FY 2019 outlier offset and apply an offset for FY 2020, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2020, consistent with current law, we are proposing to apply the rural floor budget neutrality adjustment to hospital wage indexes. In addition, our proposals to increase the wage index values for hospitals with a wage index value in the lowest quartile of the wage index values across all hospitals and offset the estimated increase in IPPS payments by decreasing the wage index values for hospitals with a wage index value in the highest quartile of the wage index values across all hospitals (high wage index hospitals) are adjustments applied to hospital wage indexes. We refer readers to section III.N. of the preamble of this proposed rule for a detailed discussion. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the FY 2020 wage index for the rural floor.

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2020, we are proposing to continue to use the national labor-related and nonlabor-related shares (which are based on the 2014-based hospital market basket) that were used in FY 2019. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2020, as discussed in section III. of the preamble of this proposed rule, we are proposing to continue to use a labor-related share of 68.3 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the internet on the CMS website.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, we are proposing to calculate the FY 2020 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, in this proposed rule, we are proposing to use the 2014-based IPPS operating and capital market baskets for FY 2020. As discussed in section IV.B. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2020 applicable percentage increase (which for this proposed rule is based on IGI's fourth quarter 2018 forecast of the 2014-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2020) of 0.5 percentage point, which for this proposed rule is also calculated based on IGI's fourth quarter 2018 forecast.

Based on IGI's 2018 fourth quarter forecast of the hospital market basket increase (as discussed in Appendix B of this proposed rule), the forecast of the hospital market basket increase for FY 2020 for this proposed rule is 3.2 percent. As discussed earlier, for FY 2020, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section IV.B. of the preamble of this proposed rule for a complete discussion on the FY 2020 inpatient hospital update to the standardized amount. We also refer readers to the table above for the four possible applicable percentage increases that would be applied to update the national standardized amount. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2020 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2020 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal**

Register for public comment. Our recommendation on the update factors is set forth in Appendix B of this proposed rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the proposed FY 2020 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: Include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs at the time of this proposed rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS-excluded cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- As in the past, we are proposing to adjust the FY 2020 standardized amount to remove the effects of the FY 2019 geographic reclassifications and outlier payments before applying the FY 2020 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2020 payment policies.
- We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We also remove organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.
- The participation of hospitals under the BPCI (Bundled Payments for Care Improvement) Advanced Model started on October 1, 2018. The BPCI Advanced Model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in the BPCI Advanced Model in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced Model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced Model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.

For FY 2020, consistent with how we treated hospitals that participated in the BPCI Advanced Model in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41259), we are proposing to include all applicable data from subsection (d) hospitals participating in the BPCI Advanced Model in our IPPS payment modeling and ratesetting calculations. We believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced Model in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving regular IPPS fee-for-service payments under section 1886(d) of the Act. For the same reasons, we also are proposing to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

- Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2020 and subsequent years, we are proposing to apply a proposed proxy based on the prior fiscal year hospital readmissions payment adjustment (for FY 2020, this would be FY 2019 final

adjustment factors) and a proposed proxy based on the prior fiscal year hospital VBP payment adjustment (for FY 2020, this would be FY 2019 final adjustment factors) on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we are proposing to apply a proxy readmissions payment adjustment factor and a proxy hospital VBP payment adjustment factor from the prior final rule on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For the purpose of calculating the proposed proxy FY 2020 readmissions payment adjustment factors, for both this proposed rule and the final rule, as discussed in section IV.H. of the preamble of this proposed rule, we are proposing to use the proportion of dually-eligible Medicare beneficiaries, excess readmission ratios, and aggregate payments for excess readmissions from the prior fiscal year's applicable period because, at the time of the development of this proposed rule and the final rule, hospitals will not yet have had the opportunity to review and correct the data (program calculations based on the proposed FY 2020 applicable period of July 1, 2015 to June 30, 2018) before the data are made public under our policy regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act. (For additional information on our general policy for the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53400) and section IV.G. of the preamble of this proposed rule.)

In addition, for FY 2020, for the purpose of modeling aggregate payments when determining all budget neutrality factors, we are proposing to use proxy hospital VBP payment adjustment factors for FY 2020 that are based on data from the prior fiscal year's applicable period because hospitals have not yet had an opportunity to review and submit corrections for their data from the FY 2020 performance period. (For additional information on our policy regarding the review and correction of hospital-specific measure rates under the Hospital VBP Program, consistent with section 1886(o)(10)(A)(ii) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53578 through 53581), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74544 through 74547), and the Hospital Inpatient VBP final rule (76 FR 26534 through 26536).)

- The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, will be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2020 (as we did for the last 6 fiscal years), we are proposing to include estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

- When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.F. of the preamble of this proposed rule and below, we are proposing to continue to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are proposing to include estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV.F. of the preamble of this proposed rule, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, we are proposing to continue to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

- We are proposing to include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2020. Similar to FY 2019, we are including this adjustment based on data on the prior year's performance. Payments for hospitals will be estimated based on the proposed applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2020.

- In our determination of all proposed budget neutrality factors described in section II.A.4. of this Addendum, we use transfer-adjusted discharges. Specifically, we calculated the transfer-adjusted discharges using the statutory expansion of the postacute care transfer policy to include discharges to hospice care by a hospice program as discussed in section IV.A.2.b. of the preamble of this proposed rule.

a. Proposed Recalibration of MS–DRG Relative Weights

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.H. of the preamble of this proposed rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate

payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For FY 2020, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2018 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2019 labor-related share percentages, the FY 2019 relative weights, and the FY 2019 pre-reclassified wage data, and applied the proposed FY 2020 hospital readmissions payment adjustments and estimated FY 2020 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2019 labor-related share percentages, the proposed FY 2020 relative weights, and the FY 2019 pre-reclassified wage data, and applied the proposed FY 2020 hospital readmissions payment adjustments and estimated FY 2020 hospital VBP payment adjustments applied above.

Based on this comparison, we computed a proposed budget neutrality adjustment factor equal to 0.998768 and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we also are proposing to apply the MS–DRG reclassification and recalibration budget neutrality factor of 0.998768 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2019.

b. Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2020, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this proposed rule.

To compute a proposed budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2018 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2020 relative weights and the FY 2019 pre-reclassified wage indexes, applied the FY 2019 labor-related share of 68.3 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proposed FY 2020 hospital readmissions payment adjustment and the estimated FY 2020 hospital VBP payment adjustment; and
- Aggregate payments using the proposed FY 2020 relative weights and the proposed FY 2020 pre-reclassified wage indexes, applied the proposed labor-related share for FY 2020 of 68.3 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proposed FY 2020 hospital readmissions payment adjustments and estimated FY 2020 hospital VBP payment adjustments applied above.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the proposed payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2019 to FY 2020. By applying this methodology, we determined a proposed budget neutrality adjustment factor of 1.000915 for proposed changes to the wage index.

c. Reclassified Hospitals—Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that, with regard to the requirement under section 1886(d)(8)(C)(iii) of the Act, in our calculation of a proposed budget neutrality adjustment factor, we applied the provisions of our proposal discussed in section III.N. of the preamble of this proposed rule to exclude the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103) from the calculation of ''the wage index for rural areas in the State in which the county is located.'' We refer readers to the FY 2015 IPPS final rule (79 FR 50371 through 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality adjustment factor for FY 2020, we used FY 2018 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2020 labor-related share percentages, the proposed FY 2020 relative weights, and the proposed FY 2020 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the proposed FY 2020 hospital readmissions payment adjustments and the estimated FY 2020 hospital VBP payment adjustments; and
- Aggregate payments using the proposed FY 2020 labor-related share percentages, the proposed FY 2020 relative weights, and the proposed FY 2020 wage data after such

reclassifications, and applied the same proposed FY 2020 hospital readmissions payment adjustments and the estimated FY 2020 hospital VBP payment adjustments applied above.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this proposed rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks proposed for FY 2020, and apply the proposed policies explained in section III. of the preamble of this proposed rule. Based on these simulations, we calculated a proposed budget neutrality adjustment factor of 0.986451 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2020 budget neutrality adjustment factor was applied to the proposed standardized amount after removing the effects of the FY 2019 budget neutrality adjustment factor. We note that the proposed FY 2020 budget neutrality adjustment reflects FY 2020 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this proposed rule.

d. Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) is equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index. We note, as discussed in section III.N. of the preamble of this proposed rule, we are proposing to calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103).

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2020, we are proposing to calculate a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the proposed FY 2020 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2020 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2020 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); San German, PR (CBSA 41900); and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the proposed national rural floor budget neutrality adjustment factor, we used FY 2018 discharge data to simulate payments and the proposed post-reclassified national wage indexes and compared the following:

- National simulated payments without the proposed national rural floor; and
- National simulated payments with the proposed national rural floor.

Based on this comparison, we determined a proposed national rural floor budget neutrality adjustment factor of 0.996316. The national adjustment was applied to the national wage indexes to produce a proposed national rural floor budget neutral wage index.

e. Proposed Rural Community Hospital Demonstration Program Adjustment

In section IV.K. of the preamble of this proposed rule, we discuss the Rural Community Hospital Demonstration program, which was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed below). We make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. We refer readers to section IV.K. of the preamble of this proposed rule for complete details regarding the Rural Community Hospital Demonstration.

With regard to budget neutrality, as mentioned earlier, we make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration are budget neutral, as required under section 410A(c)(2) of Public Law 108–173. For FY 2020, the total amount that we are proposing to apply to make an adjustment to the standardized amounts to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral is $47,038,507. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2020, we computed a proposed factor of 0.999580 for the Rural Community Hospital Demonstration budget neutrality adjustment that will be applied to the IPPS standard Federal payment rate. We refer readers to section IV.K. of the preamble of this proposed rule for complete details regarding the calculation of the amount we are applying to make an adjustment to the standardized amount.

We note that, as discussed in section IV.K. of the preamble of this proposed rule, if updated or additional data become available prior to issuance of the FY 2020 IPPS/LTCH PPS final rule, we would use those data to the extent appropriate to determine the budget neutrality offset amount for FY 2020. We refer readers to section IV.K. of the preamble of this proposed rule for complete details regarding the availability of additional data prior to the FY 2020 IPPS/LTCH PPS final rule.

f. Proposed Policy for Lowest and Highest Quartile Wage Index Hospitals

As discussed in section III.N. of the preamble of this proposed rule, to address wage index disparities, we are proposing to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals. In addition, under our proposal, in order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile, we are proposing to decrease the wage index values for hospitals with a wage index value above the 75th percentile wage index value across all hospitals (high wage index hospitals). We note that this budget neutrality adjustment is applied to the wage index and not to the standardized amount. In addition, we are proposing that our proposed policy to increase the wage index for hospitals with wage indexes below the 25th percentile would be budget neutral using our authority under both section 1886(d)(3)(E) of the Act, which gives the

Secretary broad authority to adjust for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, and requires those adjustments to be budget neutral, and our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act. We refer readers to section III.N. of the preamble of this proposed rule for a complete discussion regarding this proposal.

g. Proposed Transition Budget Neutrality Adjustment Reflecting the Proposed FY 2020 Wage Index Changes

In section III.N. of the preamble of this proposed rule, we state that we recognize that, absent further adjustments, the combined effect of the proposed changes to the FY 2020 wage index could lead to significant decreases in the wage index values for some hospitals depending on the data for the final rule. Therefore, for FY 2020, we are proposing a transition wage index to help mitigate any significant decreases in the wage index values of hospitals compared to their final wage indexes for FY 2019. Specifically, we are proposing to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019. In other words, we are proposing that a hospital's final wage index for FY 2020 would not be less than 95 percent of its final wage index for FY 2019. For FY 2020, we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to apply a budget neutrality adjustment to the standardized amount so that our proposed transition for hospitals negatively impacted (described in section III.N.3.d. of the preamble of this proposed rule) is implemented in a budget neutral manner. We refer readers to section III.N. of the preamble of this proposed rule for a complete discussion regarding this proposal.

To calculate a proposed transition budget neutrality adjustment factor for FY 2020, we used FY 2018 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2020 labor-related share percentages, the proposed FY 2020 relative weights, and the proposed FY 2020 wage index for each hospital after adjusting the wage indexes under the proposed policy for lowest and highest quartile wage index hospitals but without the proposed 5-percent cap, and applied the proposed FY 2020 hospital readmissions payment adjustments and the estimated FY 2020 hospital VBP payment adjustments, and the proposed operating outlier reconciliation adjusted outlier percentage; and
- Aggregate payments using the proposed FY 2020 labor-related share percentages, the proposed FY 2020 relative weights, and the proposed FY 2020 wage index for each hospital after adjusting the wage indexes under the proposed policy for lowest and highest quartile wage index hospitals and with the proposed 5-percent cap, and applied the same proposed FY 2020 hospital readmissions payment adjustments and the estimated FY 2020 hospital VBP payment adjustments applied above, and the proposed operating outlier reconciliation adjusted outlier percentage.

This proposed FY 2020 budget neutrality adjustment factor was applied to the proposed standardized amount. Based on this comparison, we determined a proposed transition budget neutrality adjustment factor of 0.998349. We note that Table 2 associated with this proposed rule (which is available via the internet on the CMS website) contains the proposed wage index by provider before adjusting the wage indexes under the proposed policy for lowest and highest quartile wage index hospitals and the proposed 5-percent cap and the proposed wage index by provider after the application of these proposals.

h. Proposed Adjustment for FY 2020 Required Under Section 414 of Public Law 114–10 (MACRA)

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. (As noted in the FY 2018 IPPS/LTCH PPS proposed and final rules, section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted December 13, 2016, reduced the adjustment for FY 2018 from 0.5 percentage points to 0.4588 percentage points.) Therefore, for FY 2020, we are proposing to implement the required +0.5 percent adjustment to the standardized amount. This is a permanent adjustment to the payment rates.

i. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2020 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. Similar to prior years, when setting the outlier threshold, we compute the percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. As discussed in the next section, for FY 2020 we are proposing to incorporate an estimate of outlier reconciliation when setting the outlier threshold. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier

payments may be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.htm.*

(1) Proposed Methodology To Incorporate an Estimate of Outlier Reconciliation in the FY 2020 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. We have instructed MACs to identify for CMS any instances where: (1) A hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that cost reporting period. If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual (available on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) for complete details regarding outlier reconciliation. The regulation at § 412.84(m) further states that at the time of any outlier reconciliation under § 412.84(i)(4), outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Section 20.1.2.6 of Chapter 3 of the Medicare Claims Processing Manual contains instructions on how to assess the time value of money for reconciled outlier amounts.

If the operating CCR of a hospital subject to outlier reconciliation is lower at cost report settlement compared to the operating CCR used for payment, the hospital will owe CMS money because it received an outlier overpayment at the time of claim payment. Conversely, if the operating CCR increases at cost report settlement compared to the operating CCR used for payment, CMS will owe the hospital money because the hospital outlier payments were underpaid. In prior fiscal years, commenters have requested that CMS incorporate outlier reconciliation in the development of the outlier threshold.

As we have stated in prior rulemaking, outlier reconciliation is a function of the cost report, and MACs record the outlier reconciliation amount on each provider's cost report. Therefore, as the MACs continue to perform these outlier reconciliations, they record these amounts on the cost report, which are then publicly available through the HCRIS database. Therefore, the outlier reconciliation data used in the following proposed process would be publicly available through the cost report.

In the FY 2004 IPPS final rule (68 FR 45476 through 45477), we included an estimate for outlier reconciliation that identified and adjusted the CCRs of hospitals in our calculation of the outlier fixed loss threshold. However, outlier cases are difficult to predict with regard to their occurrence for any individual hospital. Generally, an outlier payment is made if the estimated costs of the case exceed the sum of the outlier threshold plus the relevant payment amounts. There are many different variables that determine whether a case will be eligible for an outlier payment, including the CCR, the estimated costs of the case, the payment amounts, and the outlier threshold itself. We refer readers to section II.C.1. of this Addendum for additional detail regarding how the outlier payment is computed. In addition, predicting both the specific hospitals that will have outlier payments reconciled and the dollar amount of any such outlier reconciliation is difficult, which makes incorporating reconciliation into the modeling of the outlier threshold challenging.

In the FY 2019 IPPS/LTCH PPS final rule and other prior rulemaking, we have stated that we continue to believe that, due to the policy implemented in the June 9, 2003 Outlier Final Rule (68 FR 34494), CCRs will no longer fluctuate as significantly and, therefore, few hospitals will actually have their outlier payments reconciled upon cost report settlement. In addition, we stated that it is difficult to predict the specific hospitals that will have fluctuating CCRs and outlier payments reconciled in any given year. In the FY 2019 IPPS/LTCH PPS final rule, in response to comments expressing concern with CMS' decision not to consider outlier reconciliation in developing the outlier threshold, we stated that we intended to revisit this issue in next year's proposed rule (that is, this FY 2020 proposed rule) as we continue to consider the feasibility of including outlier reconciliation in the modeling of the outlier threshold.

Since the issuance of the FY 2019 IPPS/LTCH PPS final rule, we have continued to consider how outlier reconciliation could be included in the modeling of the outlier threshold. Rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation for FY 2020, we believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We believe this proposed methodology would address concerns on the impact of outlier reconciliation on the modeling of the outlier threshold.

We also believe the cost report data available in the HCRIS may be sufficiently complete for certain historical fiscal years to allow for calculating an estimate of outlier reconciliation for FY 2020. We issued Change Request 7192 on December 3, 2010 (available via the internet on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2111CP.pdf*) which updated a utility to reprice outlier claims for purposes of outlier reconciliation. Prior to this update, cost reports subject to outlier reconciliation were being held open until there was a mechanism to perform the outlier reconciliation. The outlier reconciliation amounts on the cost report are reflected in HCRIS once the cost report is final settled. As MACs began performing the outlier reconciliations, they were able to final settle many of these cost reports and the data for outlier reconciliation began to become available in HCRIS. However, even with a utility available beginning in 2010, not all cost reports were final settled for reasons other than outlier reconciliation. Therefore, HCRIS may not have reflected all of the hospitals subject to outlier reconciliation. We believe that many of these other reasons for the delay in cost reports being final settled have now been resolved. In contrast to prior years, HCRIS now contains more final settled cost reports that include outlier reconciliation, in particular for FY 2014, as we discuss below, which can be used to develop an annual estimate of total dollars related to outlier reconciliation payments based on this historical cost report data. Therefore, for FY 2020, we are proposing to incorporate into the outlier model the total outlier reconciliation dollars based on historical data. We are providing below a step-by-step explanation of how we are proposing to incorporate these dollars into the model.

Currently, outlier reconciliation is among the last steps before the cost

report is final settled. In order to determine if a hospital meets the outlier reconciliation criteria, all cost report adjustments must be finalized in order to compare the final settled operating CCR from the cost report to the operating CCR used for the original claim payment. Generally, MACs attempt to have a cost report final settled 12 months after the cost report is submitted by the provider to CMS. However, there are sometimes issues or adjustments that are unique to the cost report that extend the final settlement beyond 12 months. This will delay the MAC from recording the outlier reconciliation amounts on the cost report, which will also delay the availability of these amounts in HCRIS. Because of these potential delays, we are proposing to use the historical outlier reconciliation amounts from the FY 2014 cost reports (cost reports with a begin date on or after October 1, 2013, and on or before September 30, 2014), which are currently the most recent and complete set of outlier reconciliation data, which are finalized and/or approved by the MAC as of the time of development of this FY 2020 proposed rule. We note that approximately 90 percent of the FY 2014 cost reports are final settled, as compared to approximately 60 percent of the FY 2015 cost reports that are final settled. As of the December 2018 HCRIS, 16 of the FY 2014 cost reports and 8 of the FY 2015 cost reports had completed outlier reconciliation amounts. Therefore, we believe that the FY 2014 cost reports provide the most recent and complete available data to estimate the effect of outlier reconciliation dollars on the outlier cost threshold. We considered using FY 2015 cost report data. However, because, as previously noted, the FY 2015 and later years cost reports have a larger percent of not final settled cost reports, outlier reconciliation dollars for these years may not be sufficiently available in the HCRIS. Therefore, we currently believe that it may not be appropriate to use those more recent cost reports to estimate outlier reconciliation for the FY 2020 proposed and final rules. In order to prospectively determine the outlier threshold, we are proposing to use the FY 2014 cost reports from the most recent publically available HCRIS extract at the time of development of the proposed and final rules. For this FY 2020 proposed rule, we used the December 2018 HCRIS extract to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2020 final rule, we are proposing to use the latest quarterly HCRIS extract that is publically available at the time of the development of that rule which, for FY 2020, would be the March 2019 extract. We believe hospitals that have a FY 2014 cost report approved for outlier reconciliation will have had their cost reports final settled by the issuance of this proposed rule and, therefore, would have outlier reconciliation estimates available for use in the FY 2020 final rule.

We are proposing the following methodology to incorporate a projection of outlier payment reconciliations for the FY 2020 outlier threshold calculation.

Step 1.—Use the Federal FY 2014 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude sole community hospitals (SCHs) that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We used the December 2018 HCRIS extract for this proposed rule and expect to use the March 2019 HCRIS extract for the FY 2020 final rule.

Step 2.—Calculate the aggregate amount of historical total of operating outlier reconciliation dollars (Worksheet E, Part A, Line 2.01) using the Federal FY 2014 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total Federal operating payments using the Federal FY 2014 cost reports from Step 1. The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04), outlier payments (Worksheet E, Part A, Line 2 and Line 2.02), and the outlier reconciliation payments (Worksheet E, Part A, Line 2.01). We note that a negative amount on Worksheet E, Part A, Line 2.01 for outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments for FY 2014. This percentage amount would be used to adjust the outlier target for FY 2020 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we are proposing to target 5.1 percent minus the percentage determined in Step 4 in determining the outlier threshold. Using the FY 2014 cost reports based on the December 2018 HCRIS extract, because the aggregate outlier reconciliation dollars from Step 2 are negative, we are targeting an amount higher than 5.1 percent for outlier payments for FY 2020 under our proposed methodology.

For this FY 2020 proposed rule, based on the December 2018 HCRIS, 16 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $24,433,087 (Step 2). The total Federal operating payments based on the December 2018 HCRIS was $82,969,541,296 (Step 3). The ratio (Step 4) is a negative 0.029448 percent, which, when rounded to the second digit, is negative 0.03 percent. Therefore, for FY 2020, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.13 percent [5.1 percent − (− .03 percent)]. When the percentage of operating outlier reconciliation dollars to total Federal operating payments is negative (such is the case when the aggregate amount of outlier reconciliation is negative), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2) of this Addendum, we provide the FY 2020 outlier threshold as calculated for this proposed rule both with and without including this proposed percentage estimate of operating outlier reconciliation.

As explained earlier, we believe this is an appropriate method to include outlier reconciliation dollars in the outlier model because it uses the total outlier reconciliation dollars based on historic data rather than predicting which specific hospitals will have outlier payments reconciled for FY 2020. However, we would continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. In the past, the outlier offset was six decimals because we targeted and set the threshold at 5.1 percent by adjusting the standardized amount by the outlier offset until operating outlier payments divided by total operating Federal payments plus operating outlier payments equaled approximately 5.1 percent (this approximation resulted in an offset beyond three decimals). However, under our proposed methodology, we believe a three decimal offset of 0.949 reflecting 5.1 percent is appropriate rather than the

unrounded six decimal offset that we have calculated for prior fiscal years. Specifically, as discussed in section II.A.5. of this Addendum, we are proposing to determine an outlier adjustment by applying a factor to the standardized amount that accounts for the projected proportion of total estimated FY 2020 operating Federal payments paid as outliers. Our proposed modification to the outlier threshold methodology is designed to adjust the total estimated outlier payments for FY 2020 by incorporating the projection of negative outlier reconciliation. That is, under this proposal, total estimated outlier payments for FY 2020 would be the sum of the estimated FY 2020 outlier payments based on the claims data from the outlier model and the estimated FY 2020 total operating outlier reconciliation dollars. We believe the proposed methodology would more accurately estimate the outlier adjustment to the standardized amount by increasing the accuracy of the calculation of the total estimated FY 2020 operating Federal payments paid as outliers. In other words, the net effect of our outlier proposal to incorporate a projection for outlier reconciliation dollars into the threshold methodology would be that FY 2020 outlier payments (which include the estimated recoupment percentage for FY 2020 of 0.03 percent) would be 5.1 percent of total operating Federal payments plus total outlier payments. Therefore, the operating outlier offset to the standardized amount is 0.949 (1 − 0.051).

Although we are not making any proposals with respect to the methodology for FY 2021 and subsequent fiscal years, the above-described proposed methodology could advance by one year the cost reports used to determine the historical outlier reconciliation (for example, for FY 2021, the FY 2015 outlier reconciliations would be expected to be complete). We are considering additional options in order to have available more recent estimates of outlier reconciliation for future rulemaking.

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the proposed adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we are proposing to reduce the FY 2020 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. As such, any reconciliation also applies to capital outlier payments. As part of our proposal for FY 2020 to incorporate into the outlier model the total outlier reconciliation dollars from the most recent and most complete fiscal year cost report data, we also are proposing to adjust our estimate of FY 2020 capital outlier payments to incorporate a projection of capital outlier reconciliation payments when determining the adjustment factor to be applied to the capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers. To do so, we are proposing to use the following methodology, which generally parallels the proposed methodology to incorporate a projection of operating outlier reconciliation payments for the FY 2020 outlier threshold calculation.

Step 1.—Use the Federal FY 2014 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude SCHs that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We used the December 2018 HCRIS extract for this proposed rule and expect to use the March 2019 HCRIS extract for the FY 2020 final rule.

Step 2.—Calculate the aggregate amount of the historical total of capital outlier reconciliation dollars (Worksheet E, Part A, Line 93, Column 1) using the Federal FY 2014 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total capital Federal payments using the Federal FY 2014 cost reports from Step 1. The total capital Federal payments consist of the capital DRG payments, including capital indirect medical education (IME) and capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation payments (Worksheet E, Part A, Line 93, Column 1). We note that a negative amount on Worksheet E, Part A, Line 93 for capital outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments for FY 2014. This percentage amount would be used to adjust the estimate of capital outlier payments for FY 2020 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, we are proposing that the estimate of capital outlier payments for FY 2020 would be determined by adding the percentage in Step 4 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments. We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a ''target'' percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 4 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.) Because the aggregate capital outlier reconciliation dollars from Step 2 are negative, the estimate of capital outlier payments for FY 2020 under our proposed methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold.

For this FY 2020 proposed rule, the estimated percentage of FY 2020 capital outlier payments otherwise determined using the shared outlier threshold is 5.39 percent (estimated capital outlier payments of $433,416,367 divided by

(estimated capital outlier payments of $433,416,367 plus the estimated total capital Federal payment of $7,603,919,535)). Based on the December 2018 HCRIS, 16 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $3,860,075 (Step 2). The total Federal capital payments based on the December 2018 HCRIS was $7,506,907,042 (Step 3) which results in a ratio (Step 4) of −0.05 percent. Therefore, for FY 2020, taking into account projected capital outlier reconciliation payments under our proposed methodology would decrease the estimated percentage of FY 2020 aggregate capital outlier payments by 0.05 percent.

As explained in our discussion of the outlier threshold methodology above, we believe this is an appropriate method to include capital outlier reconciliation dollars in the estimated percentage of capital outlier payments because it uses the total outlier reconciliation dollars based on historic data rather than predicting which specific hospitals will have outlier payments reconciled for FY 2020. As discussed in section III.A.2. of this Addendum, we are proposing to incorporate the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2020.

We are inviting public comment on our proposed methodology for projecting the estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed-loss cost outlier threshold and our proposed methodology for projecting the estimate of capital outlier reconciliation and incorporating that estimate into the modeling of the estimate of FY 2020 capital outlier payments for purposes of determining the capital outlier adjustment factor.

(2) Proposed FY 2020 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the proposed FY 2020 outlier threshold, we simulated payments by applying proposed FY 2020 payment rates and policies using cases from the FY 2018 MedPAR file. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described below) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the proposed FY 2020 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2018 to FY 2020. To produce the most stable measure of charge inflation, we applied the following inclusion and exclusion criteria of hospitals claims in our measure of charge inflation:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals who have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate-of-change in charges per case. We note this is consistent with the methodology used since FY 2014 and are providing this as a technical clarification.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years (for example, FY 2018 to FY 2020). Specifically, under the methodology we have used since FY 2014, we compare the average charge per case from the latest 12 month period of MedPAR claims data available at the time of the proposed rule and the final rule to the average charge per case for the 12 month period from the prior year. For example, for the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20581), we used the December 2017 update of MedPAR claims data to calculate the average charges per case for the periods of January through December for CYs 2016 and 2017. Because the publicly released MedPAR claims do not contain claims beyond the end of the Federal fiscal year, the data for the last quarter of CY 2017 were not included in the publicly available December 2017 release. As we have in prior rulemaking, we included in the FY 2019 proposed rule a table grouping the claims data used in the calculation by quarter, and also made available on the CMS website more detailed summary tables by provider with the monthly charges that were used to compute the charge inflation factor.

As summarized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41718), we have continued to receive comments expressing concern with what commenters stated was a lack of transparency with respect to the charge inflation component of the fixed-loss threshold calculation. The commenters concluded that, in the absence of access to the data or more specific data and information about how CMS arrived at the totals used in the charge inflation calculation, their ability to comment or to review the calculation of the charge inflation factor was limited.

Another commenter stated that CMS has not made the necessary data available or any guidance that describes whether and how CMS edited such data to arrive at the total of quarterly charges

and charges per case used to measure charge inflation. Consequently, the commenter stated that the table of quarterly charges provided in the proposed rule was not useful in assessing the accuracy of the charge inflation figure that CMS used in the proposed rule to calculate the outlier threshold.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41718), we noted that we responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50375), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49779 through 49780), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57283), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38524). We also explained that we have not yet been able to restructure the files (such as ensuring that personal identification information is compliant with privacy regulations) for release with the publication of the proposed rule and the final rule, and we continue to be confronted with the dilemma of either using older data that commenters can access earlier or using the most up-to-date data which will be more accurate, but will not be available to the public until after publication of the proposed and final rules. We stated that we continue to prefer using the latest data available at the time of the development of the proposed and final rules to compute the charge inflation factor because we believe it leads to greater accuracy in the calculation of the fixed-loss cost outlier threshold. We also noted that commenters did not recommend using charge data from a different period to compute the charge inflation factor. However, we stated that, for this FY 2020 IPPS/LTCH PPS proposed rule, we are continuing to consider using data that commenters can access earlier.

For this FY 2020 IPPS/LTCH PPS proposed rule, after further consideration, we believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we would use the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS. That is, for FY 2020, we are proposing to use the charge data from Federal fiscal years 2017 and 2018 to calculate the 1-year average annual rate-of-change in charges per case for purposes of calculating both the proposed and final charge inflation factors, rather than the charge data from CYs 2017 and 2018 for purposes of calculating the proposed charge inflation factor and charge data from the periods April 1, 2017 through March 31, 2018 and April 1, 2018 through March 31, 2019 for purposes of calculating the final charge inflation factor as we would under our prior methodology. We believe there are benefits to using comparable Federal fiscal year periods rather than the most recent available data to calculate charge inflation, such as seasonality effects and the completeness of claims (that is, run-out). Specifically, under the methodology used for FYs 2014 through 2019, there is no run-out time between some of the claims and the MedPAR release. For example, under our current methodology, the most recent data available for purposes of this proposed rule would be the December 2018 MedPAR release, with the final month of charge data being December 2018, and for the FY 2020 IPPS/LTCH PPS final rule, the most recent data available would be the March 2019 MedPAR release, with the final month of charge data being March 2019. With no run-out time between the end of the claims data period and the MedPAR release, some claims are not included from the last month of the applicable MedPAR release due to factors such as when the claim is submitted and claims processing time. In comparison, there is a 3-month run-out between the end of Federal fiscal year 2018 (September 30, 2018) and the December 2018 MedPAR release (cut-off as of December 31, 2018) for the proposed rule and a 6-month run-out between the end of Federal fiscal year 2018 (September 30, 2018) and the March 2019 MedPAR release (cut off as of March 31, 2019) for the final rule, which allows for more completeness in those FY 2018 claims. In addition to the completeness of the data, we believe this would also address commenters' concerns regarding transparency with respect to the data used to calculate the charge inflation factor. Adopting a methodology that uses charge data based on Federal fiscal years would allow for the MedPAR data to be readily available after publication of the proposed and final rules.

After further consideration of the issue and for the reasons discussed above, we are proposing to use the publicly available MedPAR files for the 2 most recent Federal fiscal year time periods to calculate the charge inflation factor beginning in FY 2020. Specifically, for this proposed rule, we used the December 2017 MedPAR file of FY 2017 (October 1, 2016 through September 30, 2017) charge data (released in conjunction with the FY 2019 IPPS/LTCH PPS proposed rule) and the December 2018 MedPAR file of FY 2018 (October 1, 2017 through September 30, 2018) charge data (released in conjunction with this FY 2020 IPPS/LTCH PPS proposed rule) to compute the proposed charge inflation factor. In addition, we are proposing that, for the FY 2020 final rule, we would use the most recent available data; that is, the MedPAR files from March 2018 for the FY 2017 charge data and the MedPAR files from March 2019 for the FY 2018 charge data. Because these data are publicly available at the time of the issuance of the proposed and final rules, we are proposing that, beginning with the FY 2020 final rule, we would no longer provide the table of quarterly charges that we have included in prior rulemaking, if this proposed change to our methodology is finalized. (We note that we are providing this information in this proposed rule for comparison purposes below.) We are inviting public comments on this proposed change to our methodology to use in this proposed rule the December 2017 and December 2018 MedPAR releases for the respective FY 2017 and FY 2018 October to September applicable periods rather than the respective CY 2017 and CY 2018 January to December applicable periods for purposes of calculating the proposed charge inflation factor for the FY 2020 outlier threshold calculation.

For FY 2020, under this proposed methodology, to compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $58,355.91 ($562,621,348,420/9,641,206) from October 1, 2016 through September 31, 2017, to the average covered charge per case of $61,533.91 ($583,577,793,654/9,483,841) from October 1, 2017 through September 31, 2018. This rate-of-change was 5.4 percent (1.05446) or 11.2 percent (1.11189) over 2 years. The billed charges are obtained from the claims from the MedPAR file and inflated by the inflation factor specified above.

We also are providing below our calculation of the 1-year average annual rate-of-change in charges per case based on the December 2018 MedPAR release with applicable periods of January to December for CY 2017 and CY 2018 for comparison consistent with the methodology we used for FYs 2014 through 2019. As we did for prior rulemaking, we grouped claims by quarter and present the sum total for each time period in the table that follows. Specifically, under the methodology we used for FYs 2014

through 2019, the 1-year average annualized rate-of-change in charges per case for FY 2020 is computed by comparing the average covered charge per case of $59,137.57 ($572,976,462,154/9,688,874) from January 1, 2017 through December 31, 2017 to the average covered charge per case of $62,241.46 ($549,618,561,649/8,830,425) from January 1, 2018 through December 31, 2018. This rate-of-change was 5.2 percent (1.05249) or 10.8 percent (1.10775) over 2 years.

Quarter	Covered charges (January 1, 2017 through December 31, 2017)	Cases (January 1, 2017 through December 31, 2017)	Covered charges (January 1, 2018 through December 31, 2018)	Cases (January 1, 2018 through December 31, 2018)
Jan–Mar	$149,423,349,880	2,550,360	$155,383,152,668	2,507,345
Apr–Jun	141,253,933,908	2,407,205	144,511,911,637	2,336,261
Jul–Sep	137,549,332,685	2,328,520	138,928,539,807	2,238,344
Oct–Dec	144,749,845,681	2,402,789	110,794,957,537	1,748,475
Total	572,976,462,154	9,688,874	549,618,561,649	8,830,425

As we have done in the past, in this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to establish the proposed FY 2020 outlier threshold using hospital CCRs from the December 2018 update to the Provider-Specific File (PSF)—the most recent available data at the time of the development of this proposed rule. We are proposing to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described below to hospitals assigned the statewide average CCR. For FY 2020, we also are proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). We also are proposing that, if more recent data become available, we would use that data to calculate the final FY 2020 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we have done since FY 2014, we are proposing to adjust the CCRs from the December 2018 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2017 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2018 update of the PSF. We note that we used total transfer-adjusted cases from FY 2018 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology above, for this proposed rule, we calculated a proposed December 2017 operating national average case-weighted CCR of 0.263267 and a proposed December 2018 operating national average case-weighted CCR of 0.256730. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the proposed December 2017 operating national average case-weighted CCR from the proposed December 2018 operating national average case-weighted CCR and then dividing the result by the proposed December 2017 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.975167.

We used the same methodology proposed above to adjust the capital CCRs. Specifically, we calculated a proposed December 2017 capital national average case-weighted CCR of 0.022094 and a proposed December 2018 capital national average case-weighted CCR of 0.021121. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the proposed December 2017 capital national average case-weighted CCR from the proposed December 2018 capital national average case-weighted CCR and then dividing the result by the proposed December 2017 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.955983.

For purposes of estimating the proposed outlier threshold for FY 2020, we used a wage index that is based on the proposed FY 2020 wage index that hospitals would be paid. This includes our proposal to remove urban to rural reclassifications from the calculation of the rural floor, the frontier State floor adjustment in accordance with section 10324(a) of the Affordable Care Act, and the out-migration adjustment as added by section 505 of Public Law 108–173, and incorporates our FY 2020 wage index proposals to (1) increase the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals and offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile by decreasing the wage index values for hospitals with a wage index value above the 75th percentile wage index value across all hospitals, and (2) apply a 5-percent cap for FY 2020 on any decrease in a hospital's final wage index from the hospital's final wage index in FY 2019. If we did not take the above into account, our estimate of total FY 2020 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.13 percent of total payments (which reflects the estimate of outlier reconciliation).

As described in sections IV.G. and IV.H., respectively, of the preamble of

this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the proposed hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the proposed hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2020, we also are proposing to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2020, we are proposing to include estimated FY 2020 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are proposing to incorporate an estimate of FY 2020 outlier reconciliation in the methodology for determining the outlier threshold. Under this proposed approach, we determined a threshold of $26,994 and calculated total operating Federal payments of $90,721,309,065 and total outlier payments of $4,905,819,657. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.13 percent target, which reflects our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We note that, if calculated without applying our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the proposed threshold would be $27,154. We are proposing an outlier fixed-loss cost threshold for FY 2020 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $26,994.

(2) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for FY 2020 of $26,994 (which reflects our proposed methodology to incorporate an estimate of outlier reconciliations) would result in outlier payments that will equal 5.1 percent of operating DRG payments and 5.33 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act and as discussed above, we are proposing to reduce the FY 2020 standardized amount by 5.1 percent to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the proposed FY 2020 outlier threshold are as follows:

	Operating standardized amounts	Capital federal rate *
National	0.949	0.9466388

* The proposed adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2020 capital outlier payments for capital outlier reconciliation, as discussed above and in section II.A.4.j.(1) in the Addendum to this proposed rule.

We are proposing to apply the outlier adjustment factors to the proposed FY 2020 payment rates after removing the effects of the FY 2019 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying

separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.151 or capital CCRs greater than 0.141, or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available only via the internet on the CMS website) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the above range. These statewide average ratios would be effective for discharges occurring on or after October 1, 2019 and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable proposed statewide average capital CCRs. As previously stated, the proposed CCRs in Tables 8A and 8B would be used during FY 2020 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in Change Request 3966. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of Change Request 3966 are followed. In addition, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS website: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.*

(3) FY 2018 Outlier Payments

Our current estimate, using available FY 2018 claims data, is that actual outlier payments for FY 2018 were approximately 4.94 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2018, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 2018. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2018 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier Final Rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2019 will not be available until after September 30, 2019, we are unable to provide an estimate of actual outlier payments for FY 2019 based on FY 2019 claims data in this proposed rule. We will provide an estimate of actual FY 2019 outlier payments in the FY 2021 IPPS/LTCH PPS proposed rule.

5. Proposed FY 2020 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2020. The proposed standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 68.3 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increases for FY 2020.

The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2020 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similar to above, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the

application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2019 national standardized amounts to the proposed FY 2020 national standardized amounts. The second through fifth columns display the changes from the FY 2019 standardized amounts for each applicable proposed FY 2020 standardized amount. The first row of the table shows the updated (through FY 2019) average standardized amount after restoring the FY 2019 offsets for outlier payments and the geographic reclassification budget neutrality. The MS–DRG reclassification and recalibration and wage index budget neutrality adjustment factors are cumulative. Therefore, those FY 2019 adjustment factors are not removed from this table. Additionally, for FY 2020, we have applied the proposed budget neutrality factor for the proposed policy for lowest quartile wage index hospitals and proposed transition, described above.

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CHANGES FROM FY 2019 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2020 STANDARDIZED AMOUNTS

	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
FY 2020 Base Rate after removing: 1. FY 2019 Geographic Reclassification Budget Neutrality (0.985932) 2. FY 2019 Operating Outlier Offset (0.948999) 3. FY 2019 Rural Demonstration Budget Neutrality Factor (0.999467)	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,123.70 Nonlabor (30.4%): $1,913.93	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,123.70 Nonlabor (30.4%): $1,913.93	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,123.70 Nonlabor (30.4%): $1,913.93	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,123.70 Nonlabor (30.4%): $1,913.93
	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,743.33 Nonlabor (38%): $2,294.3	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,743.33 Nonlabor (38%): $2,294.30	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,743.33 Nonlabor (38%): $2,294.3	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,743.33 Nonlabor (38%): $2,294.3
Proposed FY 2020 Update Factor	1.027	1.003	1.019	0.995
Proposed FY 2020 MS-DRG Recalibration Budget Neutrality Factor	0.998768	0.998768	0.998768	0998768
Proposed FY 2020 Wage Index Budget Neutrality Factor	1.000915	1.000915	1.000915	1.000915
Proposed FY 2020 Reclassification Budget Neutrality Factor	0.986451	0.986451	0.986451	0.986451

Proposed FY 2020 Transition Budget Neutrality Factor	0.998349	0.998349	0.998349	0.998349
Proposed FY 2020 Operating Outlier Factor	0.949	0.949	0.949	0.949
Proposed FY 2020 Rural Demonstration Budget Neutrality Factor	0.999580	0.999580	0.999580	0.999580
Adjustment for FY 2020 Required under Section 414 of Pub. L. 114-10 (MACRA)	1.005	1.005	1.005	1.005
Proposed National Standardized Amount for FY 2020 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (68.3/31.7)	**Labor $3,977.31 Nonlabor: $1,845.99**	**Labor: $3,884.36 Nonlabor: $1,802.85**	**Labor: $3,946.33 Nonlabor: $1,831.61**	**Labor: $3,853.38 Nonlabor: $1,788.47**
Proposed National Standardized Amount for FY 2020 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $3,610.45 Nonlabor: $2,212.85**	**Labor: $3,526.07 Nonlabor: $2,161.14**	**Labor: $3,582.32 Nonlabor: $2,195.62**	**Labor: $3,497.95 Nonlabor: $2,143.90**

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B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the proposed labor-related and nonlabor-related shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2020. This section addresses two types of adjustments to the standardized amounts that are made in determining the proposed prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2020, as discussed in section IV.B.3. of the preamble of this proposed rule, we are proposing to apply a labor-related share of 68.3 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this proposed rule, we discuss the data and methodology for the proposed FY 2020 wage index.

2. Proposed Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively).

For FY 2018, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38530 through 38531), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule.

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we are proposing to continue to use the same COLA factors in FY 2020 that were used in FY 2019 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. Below is a table listing the proposed COLA factors for FY 2020.

PROPOSED FY 2020 COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Cost of living adjustment factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.25
Rest of Alaska	1.25
City and County of Honolulu	1.25
County of Hawaii	1.21
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, the next update to the COLA factors for Alaska and Hawaii would occur at the same time as the update to the labor-related share of the IPPS market basket (no later than FY 2022).

C. Calculation of the Proposed Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2020

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2020 equals the Federal rate (which includes uncompensated care payments).

Under current law, the MDH program has been extended for discharges through September 30, 2022.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section IV.F. of the preamble of this proposed rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2020 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for MDHs for FY 2020 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described below. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

1. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula below is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described above) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill, while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS–DRG and MS–DRG relative weight for each claim based on the ICD–10–CM procedure and diagnosis codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described above.

Step 3—Compute the operating and capital Federal payment rate:

Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))

Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (1 + IME + DSH)

Step 4—Determine operating and capital costs:

Operating Costs = (Billed Charges × Operating CCR)

Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)

Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + New Technology Add-On Payment Amount

Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)

Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)

Operating Outlier Payment = (Operating Costs—Operating Outlier Threshold) × Marginal Cost Factor

Capital Outlier Payment = (Capital Costs—Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment to the

total claim payment amount. As noted in the formula above, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments.

2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As noted above, the MDH program has been extended under current law for discharges occurring through September 30, 2022. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2019

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2020	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase	3.2	3.2	3.2	3.2
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	−0.8	−0.8
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	−2.4	0	−2.4
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.5	−0.5	−0.5	−0.5
Proposed Applicable Percentage Increase Applied to Standardized Amount	2.7	0.3	1.9	−0.5

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section IV.B. of the preamble of this proposed rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the proposed hospital-specific rate for an SCH or an MDH is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.998768, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate that an SCH or MDH would receive for its discharges beginning on or after October 1, 2019. We note that, in this proposed rule, for FY 2020, we are not proposing to make a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2020

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. Below we discuss the factors that we are proposing to use to determine the capital Federal rate for FY 2020, which would be effective for discharges occurring on or after October 1, 2019.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that

the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2020

In the discussion that follows, we explain the factors that we are proposing to use to determine the capital Federal rate for FY 2020. In particular, we explain why the proposed FY 2020 capital Federal rate would increase approximately 0.96 percent, compared to the FY 2019 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge would increase approximately 1.9 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed update factor for FY 2020 under that framework is 1.5 percent based on a projected 1.5 percent increase in the 2014-based CIPI, a proposed 0.0 percentage point adjustment for intensity, a proposed 0.0 percentage point adjustment for case-mix, a proposed 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a proposed forecast error correction of 0.0 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2020 CIPI projection in that same section of this Addendum. Below we describe the proposed policy adjustments that we are proposing to apply in the update framework for FY 2020.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); and
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2020, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase would equal 0.5 percent for FY 2020. The net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, the proposed net adjustment for case-mix change in FY 2020 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2018 DRG reclassification and recalibration as part of our update for FY 2020. We assume, for purposes of this adjustment, that the estimate of FY 2018 DRG reclassification and recalibration would result in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2020.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of −0.1 percentage point was calculated for the FY 2018 update, for which there are historical data. That is, current historical data indicated that the forecasted FY 2018 CIPI (1.3 percent) used in calculating the FY 2018 update factor was 0.1 percentage point higher than actual realized price increases (1.2 percent). As this does not exceed the 0.25 percentage point threshold, we are not proposing an adjustment for forecast error in the update for FY 2020.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification

of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this proposed rule, we are proposing to continue to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2020 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2020, we are proposing to use an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2013 and extending through FY 2017. Based on these data, we estimated that case-mix constant intensity declined during FYs 2013 through 2017. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity would decline during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2020. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2020.

Above we described the basis of the components we used to develop the proposed 1.5 percent capital update factor under the capital update framework for FY 2020, as shown in the following table.

PROPOSED FY 2020 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.5
Intensity	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	0.5
Projected Case-Mix Change	0.5
Subtotal	1.5
Effect of FY 2018 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Proposed Update	1.5

*The capital input price index represents the 2014-based CIPI.

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2020, we are proposing to incorporate the estimated outlier reconciliation payment amounts into the outlier threshold model. (For more details on our proposal to incorporate estimated outlier reconciliation payment amounts into the outlier threshold model, we refer readers to section II.A.4.h. of this Addendum.)

For FY 2019, we estimated that outlier payments for capital-related PPS payments would equal 5.06 percent of inpatient capital-related payments based on the capital Federal rate in FY 2019. Based on the threshold discussed in section II.A. of this Addendum, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs would equal 5.39 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2020. However, using the methodology outlined in section II.A.4.h. of this Addendum, we estimate that taking into account projected capital outlier reconciliation payments would decrease FY 2020 aggregate estimated capital outlier payments by 0.05 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 5.34 percent (5.39 percent–0.05 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2020. Accordingly, we are proposing to apply an outlier adjustment factor of 0.9466 in determining the capital Federal rate for FY 2020. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2020 would be higher than the percentage for FY 2019.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2020 outlier adjustment of 0.9466 is a 0.29 percent change from the FY 2019 outlier adjustment of 0.9494. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2020 is 0.9971 (0.9466/0.9494; calculation performed on unrounded numbers) so that the proposed outlier adjustment would decrease the FY 2020 capital Federal rate by approximately 0.29 percent compared to the FY 2019 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

In section III.N. of the preamble of this proposed rule, we discuss our proposals to address wage index disparities between high and low wage index hospitals. Specifically, we are proposing to: (1) Increase the wage index for hospitals with a wage index value below the 25th percentile wage index, where the increase in the wage index value for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals; (2) decrease the wage index for hospitals with a wage index value above the 75th percentile wage index, where the wage index value for these hospitals would be decreased by a percentage of the difference between the otherwise applicable final wage index value for a year for that hospital and the 75th percentile wage index value for that year across all hospitals in order to offset the estimated aggregate increase in payments for a fiscal year under the proposal under (1) above; (3) calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as

implemented in § 412.103) and remove urban to rural reclassifications under § 412.103 from the calculation of ''the wage index for rural areas in the State in which the county is located'' in applying the provisions of section 1886(d)(8)(C)(iii) of the Act; and (4) place a 5-percent cap in FY 2020 on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019. These proposals directly affect the GAF because it is calculated based on the hospital wage index value that is applicable to the hospital under 42 CFR part 412, subpart D (Basic Methodology for Determining Prospective Payment Federal Rates for Inpatient Operating Costs). Given these proposed changes would affect the GAFs, we are proposing to augment our historical methodology for computing the budget neutrality factor for proposed changes in the GAFs. Historically, we determine a budget neutrality factor for changes in the GAF that accounts for changes resulting from the update to the wage data, wage index reclassifications and redesignations, and the rural floor in a single step. (We note that this historical GAF budget neutrality factor does not reflect changes in the frontier State adjustment or the out-migration adjustment because these statutory adjustments to the wage index are not budget neutral.)

In light of these proposed changes to the wage index, which directly affect the GAF, we are proposing to compute a budget neutrality factor for proposed changes in the GAFs in two steps. Under our proposed 2-step methodology, we first calculate a factor to ensure budget neutrality for proposed changes to the FY 2020 GAFs due to the update to the wage data, wage index reclassifications and redesignations, including our proposal to remove urban to rural reclassifications under § 412.103 from the calculation of ''the wage index for rural areas in the State in which the county is located'' in applying the provisions of section 1886(d)(8)(C)(iii) of the Act, and the rural floor, including our proposal to calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural under § 412.103, consistent with our historical GAF budget neutrality factor methodology. In the second step, we would calculate a factor to ensure budget neutrality for proposed changes to the FY 2020 GAFs due to our proposal to increase the wage index for hospitals with a wage index value below the 25th percentile wage index, decrease the wage index for hospitals with a wage index value above the 75th percentile wage index, and place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019. In this section, we refer to these three proposals as the proposed lowest quartile hospital wage index adjustment, the proposed highest quartile hospital wage index adjustment, and the proposed 5-percent cap on wage index decreases. We discuss our proposed 2-step calculation of the GAF budget neutrality factors below.

To determine the GAF budget neutrality factors for FY 2020, we first compared estimated aggregate capital Federal rate payments based on the FY 2019 MS–DRG classifications and relative weights and the FY 2019 GAFs to estimated aggregate capital Federal rate payments based on the FY 2019 MS–DRG classifications and relative weights and the FY 2020 GAFs without incorporating the effects on the GAFs of our proposed lowest quartile hospital wage index adjustment, the proposed highest quartile hospital wage index adjustment, and the proposed 5-percent cap on wage index decreases. To achieve budget neutrality for these proposed changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9999 for FY 2020. Next, we compared estimated aggregate capital Federal rate payments based on the FY 2020 GAFs with and without incorporating the effects on the GAFs of the proposed lowest quartile hospital wage index adjustment, the proposed highest quartile hospital wage index adjustment, and the proposed 5-percent cap on wage index decreases. For this calculation, estimated aggregate capital Federal rate payments were calculated using the proposed FY 2020 MS–DRG classifications and relative weights, and the proposed FY 2020 GAFs (both with and without incorporating the effects on the GAF of our proposed lowest quartile hospital wage index adjustment, the proposed highest quartile hospital wage index adjustment, and the proposed 5-percent cap on wage index decreases). (We note that, for this calculation, the GAFs included the out-migration and frontier State adjustments.) To achieve budget neutrality for the effects of the proposed lowest quartile hospital wage index adjustment, the proposed highest quartile hospital wage index adjustment, and the proposed 5-percent cap on wage index decreases on the FY 2020 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9977. Therefore, to achieve budget neutrality for the proposed changes in the GAFs, based on the proposed calculations described above, we are proposing to apply an incremental budget neutrality adjustment factor of 0.9976 (0.9999 × 0.9977) for FY 2020 to the previous cumulative FY 2019 adjustment factor.

We also compared estimated aggregate capital Federal rate payments based on the FY 2019 MS–DRG classifications and relative weights and the proposed FY 2020 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2020 MS–DRG classifications and relative weights and the proposed FY 2020 GAFs without the effects of the proposed lowest quartile hospital wage index adjustment, the proposed highest quartile hospital wage index adjustment, and the proposed 5-percent cap on wage index decreases. The proposed incremental adjustment factor for DRG classifications and changes in relative weights is 0.99998. The proposed incremental adjustment factor for MS–DRG classifications and changes in relative weights (0.99998) and for changes in the GAFs through FY 2020 (0.9976) is 0.9976 (0.99998 × 0.9976). We note that all the values are calculated with unrounded numbers.

The GAF/DRG budget neutrality adjustment factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the MS–DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor for changes in the GAF (including geographic reclassification and the proposed lowest quartile hospital wage index adjustment, the proposed highest quartile hospital wage index adjustment, and the proposed 5-percent cap on wage index decreases described above) and the MS–DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification or the proposed lowest quartile hospital wage

index adjustment and the proposed 5-percent cap on wage index decreases described above have on the other payment parameters, such as the payments for DSH or IME.

The proposed incremental GAF/DRG adjustment factor of 0.9976 (the product of the proposed incremental GAF budget neutrality adjustment factor of 0.9976 and the proposed incremental DRG budget neutrality adjustment factor of 0.99998) accounts for the MS–DRG reclassifications and recalibration and for changes in the GAFs. As noted above, it also incorporates the effects on the GAFs of FY 2020 geographic reclassification decisions made by the MGCRB compared to FY 2019 decisions and the proposed lowest quartile hospital wage index adjustment, the proposed highest quartile hospital wage index adjustment, and the proposed 5-percent cap on wage index decreases described above. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Proposed Capital Federal Rate for FY 2020

For FY 2019, we established a capital Federal rate of $459.41 (83 FR 41729, as corrected at 83 FR 49845). We are proposing to establish an update of 1.5 percent in determining the FY 2020 capital Federal rate for all hospitals. As a result of this proposed update and the proposed budget neutrality factors discussed earlier, we are proposing to establish a national capital Federal rate of $463.81 for FY 2020. The proposed national capital Federal rate for FY 2020 was calculated as follows:

- The proposed FY 2020 update factor is 1.015; that is, the proposed update is 1.5 percent.
- The proposed FY 2020 budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights and changes in the GAFs is 0.9976.
- The proposed FY 2020 outlier adjustment factor is 0.9466.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2020 affects the computation of the proposed FY 2020 national capital Federal rate in comparison to the FY 2019 national capital Federal rate. The proposed FY 2020 update factor has the effect of increasing the capital Federal rate by 1.5 percent compared to the FY 2019 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.24 percent. The proposed FY 2020 outlier adjustment factor has the effect of decreasing the capital Federal rate by 0.29 percent compared to the FY 2019 capital Federal rate. The combined effect of all the proposed changes would increase the national capital Federal rate by approximately 0.96 percent, compared to the FY 2019 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2019 CAPITAL FEDERAL RATE AND THE PROPOSED FY 2020 CAPITAL FEDERAL RATE

	FY 2019	Proposed FY 2020	Proposed change	Proposed percent change
Update Factor [1]	1.0140	1.0150	1.015	1.50
GAF/DRG Adjustment Factor [1]	0.9969	0.9976	0.9976	−0.24
Outlier Adjustment Factor [2]	0.9494	0.9466	0.9971	−0.29
Capital Federal Rate	$459.41	$463.81	1.0096	[3] 0.96

[1] The proposed update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the proposed incremental change from FY 2019 to FY 2020 resulting from the application of the proposed 0.9976 GAF/DRG budget neutrality adjustment factor for FY 2020 is a net change of 0.9976 (or −0.24 percent).

[2] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the proposed net change resulting from the application of the proposed FY 2020 outlier adjustment factor is 0.9466/0.9494 or 0.9971 (or −0.29 percent) (calculation performed on unrounded numbers).

[3] Percent change may not sum due to rounding.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2020

For purposes of calculating payments for each discharge during FY 2020, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG Weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier thresholds for FY 2020 are in section II.A. of this Addendum. For FY 2020, a case will qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.h.(1) of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the proposed fixed-loss amount of $26,994.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI

was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. For this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to use the rebased and revised IPPS operating and capital market baskets that reflect a 2014 base year. For a complete discussion of this rebasing, we refer readers to section IV. of the preamble of the FY 2018 IPPS/LTCH PPS final rule (82 FR 38170).

2. Forecast of the CIPI for FY 2020

Based on IHS Global Inc.'s fourth quarter 2018 forecast, for this proposed rule, we are forecasting the 2014-based CIPI to increase 1.5 percent in FY 2020. This reflects a projected 1.7 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 3.6 percent increase in other capital expense prices in FY 2020, partially offset by a projected 0.6 percent decline in vintage-weighted interest expense prices in FY 2020. The weighted average of these three factors produces the forecasted 1.5 percent increase for the 2014-based CIPI in FY 2020.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2020

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

The FY 2020 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, children's hospitals, the short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, RNHCIs, and extended neoplastic disease care hospitals is the estimated percentage increase in the IPPS operating market basket for FY 2020, in accordance with applicable regulations at § 413.40. Based on IGI's 2018 fourth quarter forecast, we estimated that the 2014-based IPPS operating market basket update for FY 2020 is 3.2 percent (that is, the estimate of the market basket rate-of-increase). However, we are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2020. Therefore, for children's hospitals, the 11 cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), extended neoplastic disease care hospitals, and RNHCIs, the FY 2020 rate-of-increase percentage that would be applied to the FY 2019 target amounts, in order to determine the FY 2020 target amounts is 3.2 percent.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule for the proposed updated changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2020. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2020

A. Proposed LTCH PPS Standard Federal Payment Rate for FY 2020

1. Overview

In section VII. of the preamble of this proposed rule, we discuss our proposed annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2020.

Under § 412.523(c)(3) of the regulations, for LTCH PPS FYs 2012 through 2019, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II), and 1886(m)(4) of the Act as set forth in the regulations at §§ 412.523(c)(3)(viii) through (c)(3)(xv)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) specifies that, for rate year 2020 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as ''the multifactor productivity (MFP) adjustment'') as discussed in section VII.D.2. of the preamble of this proposed rule.

This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.D.2.a. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the Proposed FY 2020 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice, for FY 2020, we are proposing to apply the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the proposed LTCH PPS standard Federal payment rate for FY 2020, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2020 LTCH PPS standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes

to the wage data and labor-related share) in accordance with § 412.523(d)(4) and a temporary budget neutrality adjustment factor (applied to LTCH PPS standard Federal payment rate cases only) for the cost of the elimination of the 25-percent threshold policy for FY 2020 (discussed in VII.D. of the preamble of this proposed rule).

In this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 2.7 percent. Accordingly, as reflected in proposed § 412.523(c)(3)(xvi), we are proposing to apply a factor of 1.027 to the FY 2019 LTCH PPS standard Federal payment rate of $41,558.68 to determine the proposed FY 2020 LTCH PPS standard Federal payment rate. Also, as reflected in proposed § 412.523(c)(3)(xvi), applied in conjunction with the provisions of § 412.523(c)(4), we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.7 percent (that is, a proposed update factor of 1.007) for FY 2020 for LTCHs that fail to submit the required quality reporting data for FY 2020 as required under the LTCH QRP. Additionally, we are proposing to apply a temporary budget neutrality adjustment factor of 0.990741 to the LTCH PPS standard Federal payment rate for the cost of the elimination of the 25-percent threshold policy for FY 2020 after removing the temporary budget neutrality adjustment factor of 0.990884 that was applied to the LTCH PPS standard Federal payment rate for the cost of the elimination of the 25-percent threshold policy for FY 2019 (or a temporary, one-time factor of 0.999856 as discussed in VII.D. of the preamble of this proposed rule). Consistent with § 412.523(d)(4), we also are proposing to apply an area wage level budget neutrality factor to the proposed FY 2020 LTCH PPS standard Federal payment rate of 1.0064747, based on the best available data at this time, to ensure that any changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal rate payments. Accordingly, we are proposing to establish an LTCH PPS standard Federal payment rate of $42,950.91 (calculated as $41,558.68 × 0.999856 × 1.027 × 1.0064747) for FY 2020 (calculations performed on rounded numbers). For LTCHs that fail to submit quality reporting data for FY 2020, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of $42,114.47 (calculated as $41,558.68 × 0.999856 × 1.007 × 1.0064747) (calculations performed on rounded numbers) for FY 2020.

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2020

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

2. Proposed Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB and a ''rural area'' is defined as any area outside of an urban area (75 FR 37246).

The CBSA-based geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the OMB labor market area delineations based on the 2010 Decennial Census data. The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. We adopted these labor market area delineations because they are based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believe that these OMB delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) of the regulations (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. OMB Bulletin No. 17–01, issued August 15, 2017, establishes the current delineations for the Nation's statistical areas, and the corresponding changes to the CBSA-based labor market areas were adopted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41731). A copy of this bulletin may be obtained on the website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*

We believe the current CBSA-based labor market area delineations as established in OMB Bulletin 17–01 and adopted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41731) will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 57298). Therefore, we are proposing to continue to use the CSBA-based labor market area delineations adopted under the LTCH PPS, effective October 1, 2019 (as adopted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41731)). Accordingly, the proposed FY 2020 LTCH PPS wage index values in Tables 12A and 12B

listed in section VI. of the Addendum to this proposed rule (which are available via the internet on the CMS website) reflect the CBSA-based labor market area delineations as described above. We noted that, as discussed in section III.A.2. of the preamble of this proposed rule, these CBSA-based delineations also are being proposed to be used under the IPPS.

3. Proposed Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH PPS market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we rebased and revised the market basket used under the LTCH PPS by adopting a 2009-based LTCH-specific market basket. In addition, beginning in FY 2013, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH-specific market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) As noted previously, we rebased and revised the 2009-based LTCH-specific market basket to reflect a 2013 base year. In conjunction with that policy, as discussed in section VII.D. of the preamble of this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to establish that the LTCH PPS labor-related share for FY 2020 is the sum of the FY 2020 relative importance of each labor-related cost category in the 2013-based LTCH market basket using the most recent available data.

Specifically, we are proposing to establish that the labor-related share for FY 2020 includes the sum of the labor-related portion of operating costs from the 2013-based LTCH market basket (that is, the sum of the FY 2020 relative importance share of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) and a portion of the relative importance of the Capital-Related cost weight from the 2013-based LTCH PPS market basket. Based on IGI's fourth quarter 2018 forecast of the 2013-based LTCH market basket, we are proposing to establish a labor-related share under the LTCH PPS for FY 2020 of 66.0 percent. (We note that a proposed labor-related share of 66.0 percent is the same as the labor-related share for FY 2019, and although the relative importance of some components of the market basket have changed, the proposed labor-related share remains at 66.0 percent when aggregating these components and rounding to one decimal.) This proposed labor-related share is determined using the same methodology as employed in calculating all previous LTCH PPS labor-related shares. Consistent with our historical practice, we also are proposing that if more recent data became available, we would use that data, if appropriate, to determine the final FY 2020 labor-related share in the final rule.

The proposed labor-related share for FY 2020 is the sum of the FY 2020 relative importance of each labor-related cost category, and would reflect the different rates of price change for these cost categories between the base year (2013) and FY 2020. The sum of the relative importance for FY 2020 for operating costs (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services) is 61.9 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (the same percentage applied to the 2009-based LTCH-specific market basket). Because the relative importance for capital-related costs under our policies is 9.0 percent of the 2013-based LTCH market basket in FY 2020, we are proposing to take 46 percent of 9.0 percent to determine the labor-related share of capital-related costs for FY 2020 (0.46×9.0). The result is 4.1 percent, which we added to 61.9 percent for the operating cost amount to determine the total proposed labor-related share for FY 2020. Therefore, we are proposing to establish that the labor-related share under the LTCH PPS for FY 2020 is 66.0 percent.

4. Proposed Wage Index for FY 2020 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41732), we calculated the FY 2019 LTCH PPS area wage index values using the same data used for the FY 2019 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2015), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2019 LTCH PPS area wage index values, consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, as discussed in this FY 2020 IPPS/LTCH PPS proposed rule, to determine the applicable area wage index values for the FY 2020 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2016, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act because these data are the most recent complete data available. We also note that these are the same data we are proposing to use to compute the proposed FY 2020 acute care hospital

inpatient wage index, as discussed in section III. of the preamble of this proposed rule. We are proposing to compute the proposed FY 2020 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, labor market area delineations, including the proposed updates, as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. We also are proposing to continue to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2020, we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data would be determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data would be determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2016 IPPS wage data that we are proposing to use to determine the proposed FY 2020 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the proposed FY 2020 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website. Likewise, based on this same FY 2016 IPPS wage data that we are proposing to use to determine the proposed FY 2020 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no IPPS wage data for the urban area of Carson City, NV (CBSA 16810). Consistent with the methodology discussed above, we calculated the proposed FY 2020 wage index value for CBSA 16810 as the average of the wage index values for all of the other urban areas within the State of Nevada (that is, CBSAs 29820 and 39900, as shown in Table 12A, which is listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

Based on the FY 2016 IPPS wage data that we are proposing to use to determine the proposed FY 2020 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a proposed LTCH PPS standard Federal payment rate wage index value for proposed rural areas with no IPPS wage data for FY 2020. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future. The proposed FY 2020 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2019, through September 30, 2020, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website.

Historically, we have calculated the LTCH PPS wage index values using unadjusted wage index values from the IPPS hospitals. Stakeholders have frequently commented on certain aspects of the wage index values and their impact on payments. In this proposed rule, we are soliciting public comments on concerns that stakeholders may have regarding the wage index used to adjust LTCH PPS payments and suggestions for possible updates and improvements to the geographic adjustment of LTCH PPS payments.

5. Proposed Budget Neutrality Adjustment for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that will be applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we apply an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

In this FY 2020 IPPS/LTCH PPS proposed rule, for FY 2020 LTCH PPS standard Federal payment rate cases, in accordance with § 412.523(d)(4), we are proposing to apply an area wage level adjustment budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the proposed adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using a methodology that is consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, we are proposing to determine an area wage level adjustment budget neutrality factor that would be applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2020 using the following methodology:

Step 1—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2019 wage index values and the FY 2019 labor-related share of 66.0 percent (as established in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41732)).

Step 2—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the proposed FY 2020 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this proposed rule and available via the internet on the CMS website) and the proposed FY 2020 labor-related share of 66.0 percent

(based on the latest available data as previously discussed in this Addendum).

Step 3—We calculated the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2019 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2020 area wage level adjustments (calculated in Step 2) to determine the proposed area wage level adjustment budget neutrality factor for FY 2020 LTCH PPS standard Federal payment rate payments.

Step 4—We then applied the proposed FY 2020 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2020 LTCH PPS standard Federal payment rate after the application of the proposed FY 2020 annual update (discussed previously in section V.A. of this Addendum).

We note that, with the exception of cases subject to the transitional blended payment rate provisions and certain temporary exemptions for certain spinal cord specialty hospitals and certain severe wound cases, under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. Because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, we only used data from claims that would have qualified for payment at the LTCH PPS standard Federal payment rate if such rate had been in effect at the time of discharge to calculate the proposed FY 2020 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor described above. Moreover, we note that the estimated proposed LTCH PPS standard Federal payment rate used in the calculations in Steps 1 through 4 above include the one-time budget neutrality adjustment factor for the estimated cost of eliminating the 25-percent threshold policy in FY 2020, as discussed in section VII.D. of the preamble of this proposed rule.

For this proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2020 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.0064747. Accordingly, in section V.A. of the Addendum to this proposed rule, to determine the proposed FY 2020 LTCH PPS standard Federal payment rate, we are proposing to apply an area wage level adjustment budget neutrality factor of 1.0064747, in accordance with § 412.523(d)(4).

C. Proposed LTCH PPS Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described. The methodology used to determine the COLA factors for Alaska and Hawaii is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. Under our current policy, we update the COLA factors using the methodology described above every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), and we last updated the COLA factors for Alaska and Hawaii published by OPM for 2009 in FY 2018 (82 FR 38539 through 38540).

We continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Therefore, in this FY 2020 IPPS/LTCH PPS proposed rule, for FY 2020, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are proposing to continue to use the COLA factors based on the 2009 OPM COLA factors updated through 2016 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2018 IPPS/LTCH PPS final rule. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii and for a discussion on the FY 2018 COLA factors, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38539 through 38540).)

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2020

Area	Proposed FY 2020
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.25
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.21
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Proposed Adjustment for LTCH PPS High Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

In order to maintain budget neutrality, consistent with the budget neutrality requirement for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 2-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended payment rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted above, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and also are used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs above the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. LTCH Total CCR Ceiling

Consistent with our historical practice, we are proposing to use the most recent data available to determine the LTCH total CCR ceiling for FY 2020 in this proposed rule. Specifically, in this proposed rule, using our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2018 update of the Provider Specific File (PSF), which is the most recent data available, we are proposing to establish an LTCH total CCR ceiling of 1.247 under the LTCH PPS for FY 2020 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48118 through 48119).)

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(C)(*2*), the current SSO policy at § 412.529(f)(4)(iii)(B), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with

§ 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this proposed rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2018 update of the PSF, we are proposing to establish LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2019, through September 30, 2020, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the internet on the CMS website). Consistent with our historical practice, we also are proposing that if more recent data become available, we would use that data to determine the LTCH PPS statewide average total CCRs for FY 2020 in the final rule.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut and Nevada have areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there was no data available from short-term, acute care IPPS hospitals to compute a rural statewide average CCR or there were no short-term, acute care IPPS hospitals or LTCHs located in these areas as of December 2018. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut and Nevada in Table 8C. Furthermore, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are using this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of HCO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation. Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to Sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010), and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. Proposed Changes to High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2020

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount and target for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been a LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We use MedPAR claims data and CCRs based on data from the most recent PSF (or from the applicable statewide average CCR if an LTCH's CCR data are faulty or unavailable) to establish an applicable fixed-loss threshold amount for LTCH PPS standard Federal payment rate cases.

In this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing to continue to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2020 using the best available data that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in this proposed rule).

Specifically, based on the most recent complete LTCH data available at this time (that is, LTCH claims data from the December 2018 update of the FY 2018 MedPAR file and CCRs from the December 2018 update of the PSF), we are proposing to determine a proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2020 of $29,997 that would result in estimated outlier payments projected to

be equal to 7.975 percent of estimated FY 2020 payments for such cases. Under this proposal, we would continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed adjusted LTCH PPS standard Federal payment rate payment and the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases of $29,997).

We note that the proposed fixed-loss amount for HCO cases that would be paid under the LTCH PPS standard Federal payment rate in FY 2020 of $29,997 is significantly higher than the FY 2019 fixed-loss amount of $27,121 (as corrected at 83 FR 49845). However, based on the most recent available data at the time of the development of this FY 2020 IPPS/LTCH PPS proposed rule, we found that the current FY 2019 HCO threshold of $27,121 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 8.24 percent of the estimated total LTCH PPS payments in FY 2018, which exceeds the 7.975 percent target by 0.265 percentage points. We continue to believe that, as discussed in detail in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38543), this increase is largely attributable to the rate-of-change (that is, increase) in the Medicare allowable charges on the claims data in addition to updates to CCRs from the March 2018 update of the PSF to the December 2018 update of the PSF. Consistent with our historical practice of using the best data available, we are proposing that, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2020 in the final rule, we would use the most recent available LTCH claims data and CCR data at the time.

4. Proposed High-Cost Outlier Payments for Site Neutral Payment Rate Cases

Under § 412.525(a), site neutral payment rate cases receive an additional HCO payment for costs that exceed the HCO threshold that is equal to 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold (80 FR 49618 through 49629). In the following discussion, we note that the statutory transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019 used a blended payment rate, which is determined as 50 percent of the site neutral payment rate amount for the discharge and 50 percent of the LTCH PPS standard Federal payment rate amount for the discharge (§ 412.522(c)(3)). As such, for FY 2020 discharges paid under the transitional payment method, the discussion below pertains only to the site neutral payment rate portion of the blended payment rate under § 412.522(c)(3)(i).

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FY 2019, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases, FY 2017 claims for these cases were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2019, at that time our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2019 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2019. In particular, in FY 2019, we established the fixed-loss amount for site neutral payment rate cases as the FY 2019 IPPS fixed-loss amount of $25,743 (as corrected at 83 FR 49845).

As noted earlier, because not all claims in the data used for this FY 2020 IPPS/LTCH PPS proposed rule were subject to the unblended site neutral payment rate, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2019 when developing a fixed-loss amount for site neutral payment rate cases for FY 2020. Because our actuaries continue to project that site neutral payment rate cases in FY 2020 will continue to mirror an IPPS case paid under the same MS–DRG, we continue to believe that it would be inappropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases paid under the IPPS. More specifically, as with FYs 2016 through 2019, our actuaries project that the costs and resource use for FY 2020 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what was found based on the historical data. (Based on the most recent FY 2018

LTCH claims data used in the development of this FY 2020 IPPS/LTCH PPS proposed rule, approximately 71 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 29 percent of LTCH cases would have been paid the site neutral payment rate for discharges occurring in FY 2018.)

For these reasons, we continue to believe that the most appropriate proposed fixed-loss amount for site neutral payment rate cases for FY 2020 is the proposed IPPS fixed-loss amount for FY 2020. Therefore, consistent with past practice, in this FY 2020 IPPS/LTCH PPS proposed rule, we are proposing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the proposed IPPS fixed-loss amount. That is, we are proposing a fixed-loss amount for site neutral payment rate cases of $26,994, which is the same proposed FY 2020 IPPS fixed-loss amount discussed in section II.A.4.j.(1) of the Addendum to this proposed rule. We continue to believe this policy would reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems. Accordingly, for FY 2020, we are proposing to calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $26,994).

In establishing a HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2020 would not result in any increase in estimated aggregate FY 2020 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments (or the portion of the blended payment rate payment for FY 2020 discharges occurring in LTCH cost reporting periods beginning before October 1, 2019) by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2020. In order to achieve this, for FY 2020, in general, we are proposing to continue to use the policy adopted for FY 2019.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate the proposed fixed-loss threshold of $26,994 results in HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2020 would not result in any increase in estimated aggregate FY 2020 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2020. In order to achieve this, for FY 2020, we are proposing to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0 − 5.1/100 = 0.949) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this proposed HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

E. Proposed Update to the IPPS Comparable Amount To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the 25-percent threshold payment adjustment policy at § 412.534 and § 412.536. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2020, as discussed in greater detail in section IV.F.3. of the preamble of this proposed rule, based on the most recent data available, our estimate of 75 percent of the amount that would

otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 67.14 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2020. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act will be adjusted to 50.36 percent (the product of 75 percent and 67.14 percent) and the resulting amount will be used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2020, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 75.36 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 50.36 percent = 75.36 percent).

Therefore, for FY 2020, we are proposing to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 75.36 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we are proposing that if more recent data become available, we would use that data to determine this factor in the final rule.

F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2020

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the proposed FY 2020 values are shown in Tables 12A through 12B listed in section VI. of the Addendum to this proposed rule and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2020 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish an LTCH PPS standard Federal payment rate for FY 2020 of $42,950.91, as discussed in section V.A. of the Addendum to this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS standard Federal payment rate for FY 2020 in the following example:

Example: During FY 2020, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in Chicago, Illinois (CBSA 16974). The proposed FY 2020 LTCH PPS wage index value for CBSA 16974 is 1.0347 (obtained from Table 12A listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a proposed relative weight for FY 2020 of 0.9602 (obtained from Table 11 listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website). The LTCH submitted quality reporting data for FY 2020 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient case in FY 2020, we computed the wage-adjusted proposed Federal prospective payment amount by multiplying the unadjusted proposed FY 2020 LTCH PPS standard Federal payment rate ($42,950.91) by the proposed labor-related share (66.0 percent) and the proposed wage index value (1.0347). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted proposed LTCH PPS standard Federal payment rate (34.0 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9602) to calculate the total adjusted proposed LTCH PPS standard Federal prospective payment for FY 2020 ($42,185.97). The table below illustrates the components of the calculations in this example.

Unadjusted Proposed LTCH PPS Standard Federal Prospective Payment Rate	$42,950.91
Proposed Labor-Related Share	× 0.660
Proposed Labor-Related Portion of the Proposed LTCH PPS Standard Federal Payment Rate	= $28,347.60
Proposed Wage Index (CBSA 16974)	× 1.0347
Proposed Wage-Adjusted Labor Share of the Proposed LTCH PPS Standard Federal Payment Rate	= $29,331.26
Proposed Nonlabor-Related Portion of the Proposed LTCH PPS Standard Federal Payment Rate ($42,950.91 × 0.340)	+ $14,603.31
Adjusted Proposed LTCH PPS Standard Federal Payment Amount	= $43,934.57
Proposed MS–LTC–DRG 189 Relative Weight	× 0.9602
Total Adjusted Proposed LTCH PPS Standard Federal Prospective Payment	= $42,185.97

VI. Tables Referenced in This Proposed Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this proposed rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2019, for the FY 2020 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available through the internet. Specifically, all IPPS tables listed below, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available through the internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules. For additional discussion of the

information included in the IPPS and LTCH PPS tables associated with the IPPS/LTCH PPS proposed and final rules, as well as prior changes to the information included in these tables, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41739 through 41740).

In addition, under the HAC Reduction Program, established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. The hospital-level data for the FY 2020 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

As discussed in section IV.G. of the preamble of this proposed rule, the proposed fiscal year readmissions payment adjustment factors, which are typically included in Table 15 of the rules, are not available at this time because hospitals have not yet had the opportunity to review and correct the data (program calculations based on the FY 2020 applicable period of July 1, 2015 to June 30, 2018) before the data are made public under our policy regarding the reporting of hospital-specific data. After hospitals have been given an opportunity to review and correct their calculations for FY 2020, we will post Table 15 (which will be available via the internet on the CMS website) to display the final FY 2020 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2019. We expect Table 15 will be posted on the CMS website in the fall of 2019.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified below should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this proposed rule are generally available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled, ''FY 2020 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download.''

Table 2.—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2020

Table 3.—Proposed Wage Index Table by CBSA—FY 2020

Table 4.—Proposed List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2020

Table 5.—Proposed List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2020

Table 6A.—New Diagnosis Codes—FY 2020

Table 6B.—New Procedure Codes—FY 2020

Table 6C.—Invalid Diagnosis Codes—FY 2020

Table 6D.—Invalid Procedure Codes—FY 2020

Table 6E.—Revised Diagnosis Code Titles—FY 2020

Table 6F.—Revised Procedure Code Titles—FY 2020

Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2020

Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2020

Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2020

Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2020

Table 6I.1.—Proposed Additions to the MCC List—FY 2020

Table 6I.2.—Proposed Deletions to the MCC List—FY 2020

Table 6J.1.—Proposed Additions to the CC List—FY 2020

Table 6J.2.—Proposed Deletions to the CC List—FY 2020

Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MS–DRG Changes—FY 2020 (Table 6P contains multiple tables, 6P.1a. through 6P.1e., that include the ICD–10–CM and ICD–10–PCS code lists relating to proposed specific MS–DRG changes. These tables are referred to throughout section II.F. of the preamble of this proposed rule.)

Table 7A.—Proposed Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2018 MedPAR Update—December 2018 GROUPER Version 36 MS–DRGs

Table 7B.—Proposed Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2018 MedPAR Update—December 2018 GROUPER Version 37 MS–DRGs

Table 8A.—Proposed FY 2020 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Proposed FY 2020 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 16.—Proposed Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2020

Table 18.—Proposed FY 2020 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2020 proposed rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1716–P:

Table 8C.—Proposed FY 2020 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2019 through September 30, 2020

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2019 through September 30, 2020

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2019 through September 30, 2020

TABLE 1A—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (68.3 PERCENT LABOR SHARE/31.7 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2020

Hospital submitted quality data and is a meaningful EHR user (update = 2.7 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = 0.3 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 1.9 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −0.5 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,977.31	$1,845.99	$3,884.36	$1,802.85	$3,946.33	$1,831.61	$3,853.38	$1,788.47

TABLE 1B—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2020

Hospital submitted quality data and is a meaningful EHR user (update = 2.7 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = 0.3 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 1.9 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −0.5 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,610.45	$2,212.85	$3,526.07	$2,161.14	$3,582.32	$2,195.62	$3,497.95	$2,143.90

TABLE 1C—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1);—FY 2020

Standardized amount	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National [1]	Not Applicable	Not Applicable	$3,610.45	$2,212.85

[1] For FY 2020, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2020

	Rate
National	$463.81

TABLE 1E—PROPOSED LTCH PPS STANDARD FEDERAL PAYMENT RATE—FY 2020

	Full update (2.7 percent)	Reduced update * (0.7 percent)
Standard Federal Rate	$42,950.91	$42,114.47

* For LTCHs that fail to submit quality reporting data for FY 2020 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also as we note below, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the proposed changes in this proposed rule, such as the proposed updates to the IPPS and LTCH PPS rates, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

We have determined that this proposed rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the proposed changes for FY 2020 acute care hospital operating and capital payments would redistribute amounts in excess of $100 million to acute care hospitals. The proposed applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated $4.67 billion increase in FY 2020 payments,

primarily driven by a combined $4.4 billion increase in FY 2020 operating payments and uncompensated care payments, and a net increase of $300 million resulting from estimated changes in FY 2020 capital payments, new technology add-on payments, and low-volume hospital payments. These proposed changes are relative to payments made in FY 2019. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments by $37 million in FY 2020 relative to FY 2019.

Our operating impact estimate includes the proposed 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this proposed rule. In addition, our operating payment impact estimate includes the proposed 2.7 percent hospital update to the standardized amount (which includes the estimated 3.2 percent market basket update less the proposed 0.5 percentage point for the multifactor productivity adjustment (MFP)). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this proposed rule.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the proposed changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this proposed rule contains a range of policies, we refer readers to the section of the proposed rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the proposed policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2020, on various hospital groups. We estimate the effects of individual proposed policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case-mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific proposed policies in the discussion of those proposed policies as needed.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 29 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland Total Cost of Care Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of March 2019, there were 3,242 IPPS acute care hospitals included in our analysis. This represents approximately 54 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,403 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, 11 cancer hospitals, 1 extended neoplastic disease care hospital, and 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of proposed changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and policy changes to the LTCH PPS for FY 2020 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2019, there were 96 children's hospitals, 11 cancer hospitals, 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, 1 extended neoplastic disease care hospital, and 16 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, 297 rehabilitation hospitals and 832 rehabilitation units, and approximately 384 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 543 psychiatric hospitals and 1,050 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the proposed rate updates discussed in this proposed rule. The impacts of the proposed changes on LTCHs are discussed in section I.J. of this Appendix.

For children's hospitals, the 11 cancer hospitals, the 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the 1 extended neoplastic disease care hospital, and RNHCIs, the proposed update of the rate-of-increase limit (or target amount) is the estimated FY 2020 percentage increase in the 2014-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's 2018 fourth quarter forecast of the 2014-based IPPS market basket increase, we are estimating the proposed FY 2020 update to be 3.2 percent (that is, the estimate of the market basket rate-of-increase). We are proposing that if more recent data become available for the final rule, we would use such data to calculate the IPPS operating market basket update for FY 2020. However, the Affordable Care Act requires an adjustment for multifactor productivity (proposed 0.5 percentage point for FY 2020), resulting in a proposed 2.7 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.B. of the preamble of this proposed rule. Children's hospitals, the 11 cancer hospitals, the 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the 1 extended neoplastic disease care hospital, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the proposed update is the percentage increase in the 2014-based IPPS operating market basket for FY 2020, estimated at 3.2 percent.

The impact of the proposed update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in

their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Proposed Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for FY 2020 for operating costs of acute care hospitals. The proposed FY 2020 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall proposed percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2020 operating payments would increase by 3.6 percent, compared to FY 2019. In addition to the proposed applicable percentage increase, this amount reflects the proposed +0.5 percentage point permanent adjustment to the standardized amount required under section 414 of MACRA. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes to each system. This section deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available claims data to enable us to estimate the impacts on payments per case of certain proposed changes in this proposed rule. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in payments per case presented in this section are taken from the FY 2018 MedPAR file and the most current Provider-Specific File (PSF) that are used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each proposed change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2018 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of the proposed payments under the capital IPPS, and the impact of the proposed payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2020 are discussed in section I.I. of this Appendix.

We discuss the following proposed changes:

- The effects of the application of the proposed applicable percentage increase of 2.7 percent (that is, a 3.2 percent market basket update with a proposed reduction of 0.5 percentage point for the multifactor productivity adjustment), and a proposed 0.5 percentage point adjustment required under section 414 of the MACRA to the IPPS standardized amount, and the proposed applicable percentage increase (including the market basket update and the proposed multifactor productivity adjustment) to the hospital-specific rates.
- The effects of the proposed changes to the relative weights and MS–DRG GROUPER.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2016, compared to the FY 2015 wage data, to calculate the proposed FY 2020 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this proposed rule) that will be effective for FY 2020.
- The effects of the proposed rural floor with the application of the national budget neutrality factor to the wage index and the proposal to calculate the FY 2020 rural floor without including the wage data of hospitals that have reclassified as rural under § 412.103.
- The effects of the proposed frontier State wage index adjustment under the statutory provision that requires hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes for FY 2020. This provision is not budget neutral.
- The effects of the proposals to increase the wage index for hospitals with wage index values below the 25th percentile wage index value (that is, the proposed lowest quartile wage index adjustment), the associated proposal to decrease the wage index for hospitals with wage index values above the 75th percentile wage index value for budget neutrality purposes (that is, the proposed highest quartile wage index adjustment), and to apply a transition policy in FY 2020 pursuant to which a 5-percent cap would be placed on any decrease in a hospital's wage index compared to its final FY 2019 wage index value (that is, the proposed 5-percent cap).
- The total estimated change in payments based on the proposed FY 2020 policies relative to payments based on FY 2019 policies, including estimated changes in outlier payments.

To illustrate the impact of the proposed FY 2020 changes, our analysis begins with a FY 2019 baseline simulation model using: The FY 2019 applicable percentage increase of 1.35 percent; the 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount; the FY 2019 MS–DRG GROUPER (Version 36); the FY 2019 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2019 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner, and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, for FY 2020, we are proposing that hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 1.9 percent. At the time this impact was prepared, 39 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2020 because they failed the quality data submission process or did not choose to participate, but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the proposed payment changes for FY 2020 using a reduced update for these hospitals.

For FY 2020, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user will be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, for FY 2020, we are proposing that hospitals that are identified as not being meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable

percentage increase of 0.3 percent. At the time this impact analysis was prepared, 211 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2020 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the proposed payment changes for FY 2020 using a reduced update for these hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive a proposed applicable percentage increase of −0.5 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time this impact was prepared, 32 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2020 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2020 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each change.

Our comparison illustrates the proposed percent change in payments per case from FY 2019 to FY 2020. Two factors not discussed separately have significant impacts here. The first factor is the proposed update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are proposing to update the standardized amounts for FY 2020 using a proposed applicable percentage increase of 2.7 percent. This includes our forecasted IPPS operating hospital market basket increase of 3.2 percent with a proposed 0.5 percentage point reduction for the multifactor productivity adjustment. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users would receive a proposed update of 1.9 percent. This proposed update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive a proposed update of 0.3 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive a proposed update of −0.5 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs and MDHs is also equal to the applicable percentage increase, or 2.7 percent, if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the proposed changes in hospitals' payments per case from FY 2019 to FY 2020 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2019 that are no longer reclassified in FY 2020. Conversely, payments may increase for hospitals not reclassified in FY 2019 that are reclassified in FY 2020.

2. Analysis of Table I

Table I displays the results of our analysis of the proposed changes for FY 2020. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,242 acute care hospitals included in the analysis.

The next four rows of Table I contain hospitals categorized according to their geographic location: All urban, which is further divided into large urban and other urban; and rural. There are 2,476 hospitals located in urban areas included in our analysis. Among these, there are 1,268 hospitals located in large urban areas (populations over 1 million), and 1,208 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 766 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2020 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban, large urban, other urban, and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 2,188, 1,283, 905, and 1,054, respectively.

The next three groupings examine the impacts of the proposed changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,127 nonteaching hospitals in our analysis, 865 teaching hospitals with fewer than 100 residents, and 250 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next three rows examine the impacts of the proposed changes on rural hospitals by special payment groups (SCHs, MDHs and RRCs). There were 380 RRCs, 305 SCHs, 149 MDHs, 143 hospitals that are both SCHs and RRCs, and 17 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total inpatient days. These data were taken from the FY 2017 or FY 2016 Medicare cost reports.

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2020 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B).

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TABLE I.—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2020

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2020 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7)[8]	All Proposed FY 2020 Changes (8)[9]
All Hospitals	3,242	3.1	0	0	0	0	0.1	0	3.5
By Geographic Location:									
Urban hospitals	2,476	3.1	0	0	-0.1	0	0.1	0	3.5
Large urban areas	1,268	3.1	-0.1	0	-0.7	-0.1	0.1	-0.2	3.4
Other urban areas	1,208	3.1	0	0	0.5	0.1	0.2	0.1	3.7
Rural hospitals	766	2.8	0.2	0.1	1	-0.1	0.1	0.4	3.6
Bed Size (Urban):									
0-99 beds	643	3	0.4	-0.1	-0.8	0	0.3	0	3.6
100-199 beds	759	3.1	0	0	-0.2	0.1	0.2	0	3.4
200-299 beds	431	3.2	0	0	0.1	0.1	0.1	0	3.4
300-499 beds	424	3.1	-0.1	0	0	0	0.1	-0.1	3.6
500 or more beds	219	3.1	-0.1	-0.1	-0.2	-0.1	0	0	3.6
Bed Size (Rural):									
0-49 beds	302	2.7	1.1	0	0.4	-0.1	0.2	0.7	4.9

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2020 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7)[8]	All Proposed FY 2020 Changes (8)[9]
50-99 beds	272	2.8	0.3	0.1	0.5	0	0.2	0.5	3.6
100-149 beds	108	2.9	0.1	0	0.9	-0.1	-0.1	0.3	3.7
150-199 beds	45	3	-0.2	0.2	1.6	-0.1	0.2	0.4	3.2
200 or more beds	39	2.9	0	0.1	1.7	0	-0.1	0.3	3
Urban by Region:									
New England	112	3.2	0.3	-0.3	1.5	0.3	0.1	1.3	1.7
Middle Atlantic	307	3.2	-0.2	-0.1	0.3	-0.2	0.1	-0.4	3.1
South Atlantic	399	3.1	0	-0.2	-0.5	-0.1	0	0	3.5
East North Central	386	3.2	0	0	-0.4	-0.2	0	-0.1	3.6
East South Central	147	3.1	-0.1	-0.1	-0.4	-0.2	0	0.9	4.5
West North Central	157	3	0.2	0.4	-0.8	-0.1	0.6	-0.1	4.2
West South Central	375	3.2	-0.3	0.1	-0.7	-0.2	0	0.1	3.5
Mountain	169	3.1	0.2	0.2	0	0.2	0.3	0	3
Pacific	374	3.1	0	0.1	0.5	0.6	0.1	-0.7	4.1
Puerto Rico	50	3.2	-2.3	-0.5	-1	0.2	0.1	12.7	13.6

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2020 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7)[8]	All Proposed FY 2020 Changes (8)[9]
Rural by Region:									
New England	20	3	0.5	-0.8	0.6	-0.1	0	0.2	2.3
Middle Atlantic	53	2.8	0.1	-0.2	0.9	-0.1	0	0	3.1
South Atlantic	120	2.9	0	0	1.4	-0.1	0	0.7	3.6
East North Central	114	2.8	0.3	0	0.9	-0.1	0	0.1	3.4
East South Central	150	3	0	0.4	1.8	-0.2	0.1	1.1	4.3
West North Central	93	2.5	0.3	0.2	0.1	0.1	0	0.1	3.3
West South Central	142	3	0.3	0	1.5	0	0.1	0.8	4.5
Mountain	50	2.6	0.6	0.3	0.1	-0.1	0.6	0	3.3
Pacific	24	2.8	0.7	0.1	1	-0.1	0	-0.2	3.6
By Payment Classification:									
Urban hospitals	2,188	3.1	0	0	-0.6	0	0.1	-0.1	3.5
Large urban areas	1,283	3.1	-0.1	0	-0.7	-0.1	0.1	-0.2	3.4

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2020 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7)[8]	All Proposed FY 2020 Changes (8)[9]
Other urban areas	905	3.1	0.1	-0.1	-0.3	0.3	0.2	0.1	3.8
Rural areas	1,054	3	0	0.1	1.5	-0.1	0.1	0.2	3.5
Teaching Status:									
Nonteaching	2,127	3.1	0.1	0	0.1	0.1	0.1	0.1	3.6
Fewer than 100 residents	865	3.2	0	0	-0.1	0	0.2	0	3.5
100 or more residents	250	3.1	-0.1	0	0	-0.2	0	-0.1	3.5
Urban DSH:									
Non-DSH	538	3.1	0.3	0	-0.3	-0.2	0.2	0	3.7
100 or more beds	1,393	3.1	0	-0.1	-0.5	0.1	0.1	-0.1	3.5
Less than 100 beds	352	3.1	0.3	-0.1	-0.8	0.1	0.1	0	3.4
Rural DSH:									
SCH	256	2.6	0.1	0	-0.1	0	0	0.2	3
RRC	442	3.1	-0.1	0.2	1.8	-0.1	0.1	0.1	3.5
100 or more beds	31	3.2	0.1	-0.6	1.1	-0.2	0	0.3	2.9

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2020 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7)[8]	All Proposed FY 2020 Changes (8)[9]
Less than 100 beds	230	2.9	0.9	-0.1	0.5	-0.1	0.2	1.3	5.1
Urban teaching and DSH:									
Both teaching and DSH	776	3.1	-0.1	-0.1	-0.7	0	0.1	-0.1	3.5
Teaching and no DSH	84	3.2	0.3	-0.1	-0.4	-0.2	0.1	-0.2	3.7
No teaching and DSH	969	3.2	0	-0.1	-0.3	0.3	0.1	0	3.5
No teaching and no DSH	359	3.1	0.3	0	-0.7	-0.1	0.2	-0.1	3.9
Special Hospital Types:									
RRC	380	3.2	0	0.1	2	-0.1	0.2	0.1	3.7
SCH	305	2.6	0.2	-0.1	-0.1	0	0	0.1	3.1
MDH	149	2.8	0.5	-0.1	0.6	-0.1	0.1	0.6	4
SCH and RRC	143	2.7	-0.1	0	0.3	0	0	0.1	2.9
MDH and RRC	17	2.9	-0.2	-0.1	0.4	-0.1	0	0.2	2.6
Type of Ownership:									

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2020 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7)[8]	All Proposed FY 2020 Changes (8)[9]
Voluntary	1,893	3.1	0	0	0	0	0.1	0	3.5
Proprietary	852	3.1	0.1	0	-0.1	0	0.1	0.2	3.6
Government	496	3	-0.1	-0.1	-0.1	0.1	0	0	3.6
Medicare Utilization as a Percent of Inpatient Days:									
0-25	596	3.1	-0.2	0.1	-0.3	0	0	-0.1	3.4
25-50	2,122	3.1	0	0	0	0	0.1	0	3.6
50-65	414	3	0.2	-0.1	0.4	0.2	0.1	0.1	3.2
Over 65	73	2.3	1.9	0.3	-0.7	-0.1	0.7	1.2	7.2
FY 2020 Reclassifications by the Medicare Geographic Classification Review Board:									
All Reclassified Hospitals	957	3.1	0	0.1	1.7	-0.1	0.1	0	3.4

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2020 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7)[8]	All Proposed FY 2020 Changes (8)[9]
Non-Reclassified Hospitals	2,285	3.1	0	0	-1	0.1	0.1	0	3.6
Urban Hospitals Reclassified	679	3.1	-0.1	0.1	1.7	-0.1	0.1	0	3.3
Urban Non-Reclassified Hospitals	1,753	3.1	0	0	-1.1	0.1	0.1	0	3.6
Rural Hospitals Reclassified Full Year	278	2.9	0	0.1	1.9	-0.1	0	0.3	3.4
Rural Non-Reclassified Hospitals Full Year	441	2.8	0.5	0	-0.4	0	0.1	0.7	4
All Section 401 Reclassified Hospitals	335	3.1	-0.1	0.2	1.7	-0.1	0.2	0.1	3.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	3.1	0.2	-0.1	1.6	-0.1	0	0.3	3.4

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2018, and hospital cost report data are from reporting periods beginning in FY 2017 and FY 2016.

[2] This column displays the payment impact of the proposed hospital rate update and other adjustments, including the proposed 2.7 percent adjustment to the national standardized amount and the proposed hospital-specific rate (the estimated 3.2 percent market basket update reduced by 0.5 percentage point for the proposed multifactor productivity adjustment), and the 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the proposed changes to the Version 37 GROUPER, the proposed changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2018 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the proposed recalibration budget neutrality factor of 0.998768 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2016 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the proposed wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The proposed wage budget neutrality factor is 1.000915.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2020 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2020. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.986451.

[6] This column displays the effects of the proposed rural floor. For FY 2020 and subsequent years, we are proposing to calculate the rural floor without including the wage data of hospitals that have reclassified as rural under § 412.103. The statute requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The proposed rural floor budget neutrality factor applied to the wage index is 0.996316.

[7] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column displays the effect of the proposal to increase the wage index for hospitals with a wage index value below the 25th percentile wage index (that is, the proposed lowest quartile wage index adjustment), the associated budget neutrality decrease to the wage index for hospitals with a wage index value above the 75th percentile (that is, the proposed highest quartile wage index adjustment), and the proposed transition policy to place a 5-percent cap on any decrease in a hospital's wage index from its final wage index in FY 2019 (that is, the proposed 5-percent cap). This column reflects the proposed budget neutrality factor of 0.998349 for the proposed 5-percent cap.

[9] This column shows the estimated change in payments from FY 2019 to FY 2020.

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a. Effects of the Proposed Hospital Update and Other Proposed Adjustments (Column 1)

As discussed in section IV.B. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 3.2 percent market basket update and the proposed reduction of 0.5 percentage point for the multifactor productivity adjustment. In addition, as discussed in section II.D. of the preamble of this proposed rule, this column includes the FY 2020 +0.5 percentage point adjustment required under section 414 of the MACRA. As a result, we are proposing to make a 3.2 percent update to the national standardized amount. This column also includes the proposed update to the hospital-specific rates which includes the proposed 3.2 percent market basket update and the proposed

reduction of 0.5 percentage point for the multifactor productivity adjustment. As a result, we are proposing to make a 2.7 percent update to the hospital-specific rates.

Overall, hospitals would experience a 3.1 percent increase in payments primarily due to the combined effects of the proposed hospital update to the national standardized amount and the proposed hospital update to the hospital-specific rate. Hospitals that are paid under the hospital-specific rate would experience a 2.7 percent increase in payments; therefore, hospital categories containing hospitals paid under the hospital-specific rate would experience a lower than average increase in payments.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the proposed recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a proposed recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2020 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2020, the MS–DRGs are calculated using the FY 2018 MedPAR data grouped to the proposed Version 37 (FY 2020) MS–DRGs. The methodology to calculate the proposed relative weights and the reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this proposed rule.

The ''All Hospitals'' line in Column 2 indicates that proposed changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 0.998768 to the standardized amount. As discussed in section II.F.14. of the preamble of this proposed rule, as a result of our comprehensive CC/MCC analysis of the diagnosis codes, we proposed changes to the severity levels of many codes. Hospital categories that generally treat cases in the higher MS–DRG severity levels, such as large urban hospitals, would experience a decrease in their payments, while hospitals that generally treat fewer of these cases would experience a slight increase in their payments under the proposed relative weights. For example, rural hospitals would experience a 0.2 percent increase in payments in part because rural hospitals tend to treat fewer cases in higher MS–DRG severity levels. Conversely, teaching hospitals with more than 100 residents would experience a slight decrease in payments of 0.1 percent as those hospitals typically treat more cases in higher MS–DRG severity levels.

c. Effects of the Proposed Wage Index Changes (Column 3)

Column 3 shows the impact of the proposed updated wage data using FY 2016 cost report data, with the application of the proposed wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2020 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01), as updated in OMB Bulletin Nos. 15–01 and 17–01. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations, based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index, to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913) for a discussion of our adoption of the CBSA updates in OMB Bulletin No. 15–01, which were effective beginning with the FY 2017 wage index, and to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 17–01 for the FY 2019 wage index.)

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2020 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2015 and before October 1, 2016. The estimated impact of the updated wage data using the FY 2016 cost report data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other proposed payment parameters constant in this simulation. That is, Column 3 shows the proposed percentage change in payments when going from a model using the FY 2019 wage index, based on FY 2015 wage data, the labor-related share of 68.3 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the proposed FY 2020 pre-reclassification wage index based on FY 2016 wage data with the labor-related share of 68.3 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters, such as use of the proposed Version 37 MS–DRG GROUPER constant. The proposed FY 2020 occupational mix adjustment is based on the CY 2016 occupational mix survey.

In addition, the column shows the impact of the application of the proposed wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2020, we are proposing to calculate the proposed wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 68.3 percent are budget neutral, without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The proposed FY 2020 wage budget neutrality factor is 1.000915 and the overall proposed payment change is 0 percent.

Column 3 shows the impacts of updating the wage data using FY 2016 cost reports. Overall, the new wage data and the labor-related share, combined with the proposed wage budget neutrality adjustment, would lead to no change for all hospitals, as shown in Column 3.

In looking at the wage data itself, the national average hourly wage would increase 1.02 percent compared to FY 2019. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the proposed 1.02 percent increase in the national average hourly wage. Of the 3,204 hospitals with wage data for both FYs 2019 and 2020, 1,620 or 50.6 percent would experience an average hourly wage increase of 1.02 percent or more.

The following chart compares the shifts in wage index values for hospitals due to the proposed changes in the average hourly wage data for FY 2020 relative to FY 2019. Among urban hospitals, 3 would experience a decrease of 10 percent or more, and 3 urban hospitals would experience an increase of 10 percent or more. Sixty-three urban hospitals would experience an increase or decrease of at least 5 percent or more but less than 10 percent. Among rural hospitals, none would experience an increase of 10 percent or more, and none would experience a decrease of 10 percent or more. Two rural hospitals would experience an increase or decrease of at least 5 percent or more but less than 10 percent. However, 750 rural hospitals would experience increases or decreases of less than 5 percent, while 2,381 urban hospitals would experience increases or decreases of less than 5 percent. Two urban hospitals and 0 rural hospitals would experience no change to their wage index. These figures reflect proposed changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural floor, the out-migration adjustment, and other wage index exceptions and adjustments. (We refer readers to sections III.G. through III.L. of the preamble of this proposed rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this proposed rule, which are available via the internet on the CMS website) is used

to adjust the labor-related share of a hospital's standardized amount, either 68.3 percent or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the proposed pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller proposed change than would occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of proposed changes in the area wage index values for urban and rural hospitals.

Proposed FY 2020 percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Increase 10 percent or more	3	0
Increase greater than or equal to 5 percent and less than 10 percent	38	2
Increase or decrease less than 5 percent	2,381	750
Decrease greater than or equal to 5 percent and less than 10 percent	25	0
Decrease 10 percent or more	3	0
Unchanged	2	0

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The proposed changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2020.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from the date the IPPS proposed rule is issued in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year (we refer readers to the discussion of our clarification of this policy in section III.I.2. of the preamble to this proposed rule.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are proposing to apply an adjustment of 0.986451 to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this proposed rule). We note that, with regard to the requirement under section 1886(d)(8)(C)(iii) of the Act, in our calculation of the proposed budget neutrality adjustment of 0.986451, we applied the provisions of our proposal discussed in section III.N. of the preamble of this proposed rule to exclude the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act from the calculation of ''the wage index for rural areas in the State in which the county is located'' (section II.A.4. of the Addendum to this proposed rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 1.0 percent. By region, all the rural hospital categories would experience increases in payments due to MGCRB reclassifications.

Table 2 listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website reflects the reclassifications for FY 2020.

e. Effects of the Proposed Rural Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011 through 2019 IPPS/LTCH PPS final rules, and this FY 2020 IPPS/LTCH PPS proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same State. We will apply a uniform budget neutrality adjustment to the wage index. Column 5 shows the effects of the proposed rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally. We have calculated a proposed FY 2020 rural floor budget neutrality factor to be applied to the wage index of 0.996316, which would reduce wage indexes by 0.37 percent.

Column 5 shows the projected impact of the proposed rural floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the post-reclassification FY 2020 wage index of providers before the rural floor adjustment and the post-reclassification FY 2020 wage index of providers with the rural floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural floor. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) would experience a decrease in payments due to the budget neutrality adjustment that is applied nationally to their wage index. We note that, as discussed in section III.N of the preamble of this proposed rule, we are proposing to calculate the FY 2020 rural floor without including the wage data of hospitals that have reclassified as rural under § 412.103. This column reflects effects of this proposed change to the rural floor calculation methodology.

We estimate that 166 hospitals would receive the rural floor in FY 2020. We note that there are approximately 87 fewer hospitals receiving the proposed rural floor in FY 2020 than in FY 2019. This is due, in part, to our proposal to calculate the rural floor for FY 2020 and subsequent fiscal years without including the wage data of hospitals that have reclassified as rural under § 412.103. This proposal would impact States whose rural floors were heavily influenced by the wage data of hospitals that reclassified under § 412.103, such as Massachusetts and Arizona. All IPPS hospitals in our model would have their wage index reduced by the proposed rural floor budget neutrality adjustment of 0.996316. We project that, in aggregate, rural hospitals would experience a 0.1 percent decrease in payments as a result of the application of the proposed rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project that, in the aggregate, hospitals located in urban areas would experience no change in payments because increases in payments to hospitals benefitting from the rural floor offset decreases in payments to nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region would experience a 0.3 percent increase in payments primarily due to the application of the rural floor in Massachusetts. Ten urban providers in Massachusetts are expected to receive the rural floor wage index value, including the rural floor budget neutrality adjustment, which would increase payments overall to hospitals in Massachusetts by an estimated $21 million. We estimate that Massachusetts hospitals would receive approximately a 0.5 percent increase in IPPS payments due to the application of the rural floor in FY 2020.

Urban Puerto Rico hospitals are expected to experience a 0.2 percent increase in payments as a result of the application of the proposed rural floor for FY 2020.

The table below shows a comparison of the payment impact of the rural floor (with budget neutrality) by State based on the proposed FY 2020 rural floor and the payment impact of the rural floor (with budget neutrality) by State based on the FY 2019 rural floor. Columns 1a through 4a in the table below reflect the FY 2019 rural floor

calculation. The FY 2019 rural floor, as published in the October 3, 2018 Final Rule Correction Notice (83 FR 49836), was calculated by including the wage data of hospitals that reclassified as rural under § 412.103. As indicated earlier, for FY 2020 and subsequent fiscal years, we are proposing to calculate the rural floor without including the wage data of hospitals that have reclassified as rural under § 412.103. Columns 1b through 4b in the table below reflect this proposed FY 2020 rural floor calculation. Columns 1a and 1b of the table display the number of IPPS hospitals located in each State in FY 2019 and FY 2020, respectively. Columns 2a and 2b display the number of hospitals in each State that received the rural floor wage index for FY 2019 (column 2a) and those that would receive the rural floor wage index for FY 2020 (column 2b). Columns 3a and 3b display the percentage change in total payments to hospitals in each State due to the application of the rural floor with national budget neutrality for FY 2019 (column 3a) and FY 2020 (column 3b). To show the percentage change in total payments for FY 2019 and FY 2020, in columns 3a and 3b, respectively, we calculated total payments using the post-reclassification wage index of providers prior to the rural floor adjustment and total payments using the post-reclassification wage index of providers with the rural floor adjustment for FY 2019 and FY 2020, respectively. The differences in those payments are reflected in columns 3a and 3b. Columns 4a and 4b display the payment amount that hospitals in each State would gain or lose due to the application of the FY 2019 rural floor with national budget neutrality (column 4a) and the estimated payment amount that hospitals in each State would gain or lose due to the application of the proposed FY 2020 rural floor with national budget neutrality (column 4b). We note that columns 2b, 3b, and 4b of this table do not include the application of the proposal to increase the wage index for hospitals with a wage index value below the 25th percentile wage index, the associated budget neutrality proposal to decrease the wage index for hospitals with a wage index value above the 75th percentile wage index, or the proposed 5-percent cap.

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Comparison of FY 2019 and Proposed FY 2020 IPPS Estimated Payments Due to Proposed Rural Floor with National Budget Neutrality								
	FY 2019 Final Rule Correction Notice				FY 2020 Proposed Rule			
State	Number of Hospitals (1a)	Number of Hospitals That Received the Rural Floor (2a)	Percent Change in Payments due to Application of Rural Floor with Budget Neutrality (3a)	Difference (in millions) (4a)	Number of Hospitals (1b)	Number of Hospitals That Would Receive the Rural Floor (2b)	Percent Change in Payments due to Application of Proposed Rural Floor with Budget Neutrality (3b)	Difference (in $ millions) (4b)
Alabama	84	2	-0.3	$ -5	84	1	-0.2	$ -3
Alaska	6	3	0.1	0	6	3	1.1	2
Arizona	56	33	1.3	26	54	2	-0.2	-3
Arkansas	45	0	-0.3	-3	46	0	-0.2	-2
California	297	59	0.4	42	297	52	0.8	102
Colorado	45	9	0.7	9	49	10	0.8	12
Connecticut	30	8	1.3	21	30	0	-0.2	-4
Delaware	6	0	-0.3	-2	6	0	-0.2	-1
Washington, D.C.	7	0	-0.3	-2	7	0	-0.2	-1
Florida	168	7	-0.3	-20	168	7	-0.2	-12
Georgia	101	0	-0.3	-8	100	1	-0.2	-5
Hawaii	12	6	-0.1	0	12	0	-0.1	0
Idaho	14	0	-0.3	-1	16	0	-0.2	-1
Illinois	125	2	-0.3	-14	126	2	-0.2	-10
Indiana	85	0	-0.3	-7	85	0	-0.2	-5
Iowa	34	0	-0.3	-3	34	3	-0.2	-2
Kansas	51	0	-0.2	-2	51	0	-0.2	-2
Kentucky	64	0	-0.3	-5	64	0	-0.2	-3
Louisiana	90	0	-0.3	-5	89	0	-0.2	-3
Maine	17	0	-0.3	-2	17	0	-0.2	-1

Comparison of FY 2019 and Proposed FY 2020 IPPS Estimated Payments Due to Proposed Rural Floor with National Budget Neutrality								
	FY 2019 Final Rule Correction Notice				FY 2020 Proposed Rule			
State	Number of Hospitals (1a)	Number of Hospitals That Received the Rural Floor (2a)	Percent Change in Payments due to Application of Rural Floor with Budget Neutrality (3a)	Difference (in millions) (4a)	Number of Hospitals (1b)	Number of Hospitals That Would Receive the Rural Floor (2b)	Percent Change in Payments due to Application of Proposed Rural Floor with Budget Neutrality (3b)	Difference (in $ millions) (4b)
Massachusetts	56	29	3.3	123	55	10	0.5	21
Michigan	94	0	-0.3	-14	94	0	-0.2	-8
Minnesota	49	0	-0.2	-6	48	0	-0.1	-4
Mississippi	59	0	-0.3	-3	59	0	-0.2	-2
Missouri	72	0	-0.2	-6	72	0	-0.1	-2
Montana	13	1	-0.2	-1	13	1	-0.2	-1
Nebraska	23	0	-0.3	-2	23	0	-0.2	-1
Nevada	22	3	0.4	3	22	2	0.6	6
New Hampshire	13	8	2.4	14	13	8	1	6
New Jersey	64	0	-0.4	-16	64	0	-0.2	-9
New Mexico	24	2	-0.2	-1	24	0	-0.1	-1
New York	149	16	-0.3	-21	146	14	-0.2	-13
North Carolina	84	0	-0.3	-9	83	0	-0.2	-6
North Dakota	6	3	0.4	1	6	3	0.6	2
Ohio	130	7	-0.3	-11	129	6	-0.2	-7
Oklahoma	79	2	-0.3	-4	79	1	0	0
Oregon	34	1	-0.2	-2	34	1	-0.1	-1
Pennsylvania	150	3	-0.3	-17	150	1	-0.2	-10
Puerto Rico	51	11	0.1	0	50	8	0.2	0
Rhode Island	11	0	-0.4	-1	11	0	-0.2	-1

Comparison of FY 2019 and Proposed FY 2020 IPPS Estimated Payments Due to Proposed Rural Floor with National Budget Neutrality								
	FY 2019 Final Rule Correction Notice				FY 2020 Proposed Rule			
State	Number of Hospitals (1a)	Number of Hospitals That Received the Rural Floor (2a)	Percent Change in Payments due to Application of Rural Floor with Budget Neutrality (3a)	Difference (in millions) (4a)	Number of Hospitals (1b)	Number of Hospitals That Would Receive the Rural Floor (2b)	Percent Change in Payments due to Application of Proposed Rural Floor with Budget Neutrality (3b)	Difference (in $ millions) (4b)
South Carolina	54	6	-0.1	-1	54	5	-0.1	-3
South Dakota	17	0	-0.2	-1	16	0	-0.1	0
Tennessee	90	6	-0.3	-7	90	6	-0.2	-4
Texas	310	13	-0.3	-18	303	9	-0.2	-12
Utah	31	0	-0.3	-2	31	0	-0.2	-1
Vermont	6	0	-0.2	0	6	0	-0.1	0
Virginia	74	1	-0.2	-6	72	5	-0.1	-2
Washington	48	3	-0.3	-7	49	3	-0.2	-4
West Virginia	29	2	-0.2	-1	29	2	-0.1	-1
Wisconsin	66	5	-0.3	-5	66	0	-0.2	-3
Wyoming	10	2	0	0	10	0	0	0

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f. Effects of the Application of the Proposed Frontier State Wage Index and Proposed Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States,'' and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and would increase

payments overall by 0.1 percent compared to the provisions not being in effect.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and 45 hospitals located in those States would receive a frontier wage index of 1.0000. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $63 million. Urban hospitals located in the West North Central region would experience an increase in payments by 0.6 percent, because many of the hospitals located in this region are frontier State hospitals.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment will receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 171 providers that would receive the out-migration wage adjustment in FY 2020. Rural hospitals generally would qualify for the adjustment, resulting in a 0.1 percent increase in payments. This provision appears to benefit section 401 hospitals and RRCs in that they would each experience a 0.2 percent increase in payments. This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase would be approximately $40 million.

g. Effects of Application of the Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed 5-Percent Transition

Column 7 shows the effects of the proposed wage index adjustment for hospitals with a wage index value below the 25th percentile wage index value, the associated budget neutrality proposal to decrease the wage index for hospitals with a wage index value above the 75th percentile wage index, and the proposed transition policy placing a 5-percent cap for FY 2020 on any decrease in a hospital's wage index from its final FY 2019 wage index. As discussed in section III.N. of the preamble to this proposed rule, we are proposing that hospitals with a wage index value below the 25th percentile wage index value would receive an increase to their wage index value of half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We also are proposing to decrease the wage index for hospitals with a wage index value above the 75th percentile in order to ensure our proposed increase to the wage index for hospitals with a wage index value below the 25th percentile is budget neutral. In addition, for FY 2020, we are proposing to apply a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019 (which would include any decrease resulting from our proposal to not include urban to rural reclassifications in the rural floor calculation).

We are proposing that the overall effect of the application of the proposed wage index adjustment for hospitals with a wage index value below the 25th percentile would be budget neutral. In order to ensure that the overall effect of the application of the proposed wage index adjustment for hospitals with a wage index value below the 25th percentile is budget neutral, we are proposing to reduce the wage index of hospitals with wage index values above the 75th percentile by a constant factor of the difference between the hospital's otherwise applicable wage index and the 75th percentile (as described in section III.N.3.b. of this proposed rule). In addition, we are proposing to implement the proposed 5-percent cap on any decrease in a hospital's wage index in a budget neutral manner under the authority at section 1886(d)(5)(I) of the Act. Therefore, for purposes of this impact analysis, we are proposing to apply a budget neutrality adjustment factor of 0.998349 to the FY 2020 standardized amount to implement the proposed 5-percent cap in a budget neutral manner.

To show the effects of the proposed lowest and highest quartile wage index adjustments and the proposed 5-percent cap, column 7 compares payments calculated with the FY 2020 proposed wage index prior to the application of: (a) The proposed adjustment for hospitals with a wage index value below the 25th percentile; (b) the proposed adjustment for hospitals with a wage index value above the 75th percentile; and (c) the proposed 5-percent cap on any decrease in a hospital's wage index to payments calculated using the FY 2020 proposed wage index *with* the above mentioned adjustments applied (that is, the proposed lowest quartile wage index adjustment, the proposed highest quartile wage index adjustment, and the proposed 5-percent cap). The combined effect of these three proposals generally benefits hospitals in rural areas. For example, we estimate that the proposed adjustments for hospitals with a wage index value below the 25th percentile wage index and above the 75th percentile wage index and the proposed 5-percent cap on any decrease in a hospital's wage index would increase payments to rural hospitals by an average of 0.4 percent. By region, rural South Atlantic and West South Central hospital categories would experience increases in payments by 0.7 and 0.8 percent, respectively. Puerto Rico providers would experience a 12.7 percent increase in payments due to the application of the proposed lowest quartile wage index adjustment because they generally have the lowest wage index values.

h. Effects of All FY 2020 Proposed Changes (Column 8)

Column 8 shows our estimate of the proposed changes in payments per discharge from FY 2019 and FY 2020, resulting from all proposed changes reflected in this proposed rule for FY 2020. It includes combined effects of the year-to-year change of the previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 3.5 percent for FY 2020 relative to FY 2019 and for this row is primarily driven by the proposed changes reflected in Column 1. Column 8 includes the proposed annual hospital update of 2.7 percent to the national standardized amount. This proposed annual hospital update includes the proposed 3.2 percent market basket update and the proposed 0.5 percentage point reduction for the multifactor productivity adjustment. As discussed in section II.D. of the preamble of this proposed rule, this column also includes the +0.5 percentage point adjustment required under section 414 of the MACRA. Hospitals paid under the hospital-specific rate would receive a 2.7 percent hospital update. As described in Column 1, the proposed annual hospital update with the proposed +0.5 percent adjustment for hospitals paid under the national standardized amount, combined with the proposed annual hospital update for hospitals paid under the hospital-specific rates, would result in a 3.5 percent increase in payments in FY 2020 relative to FY 2019. This estimated increase also reflects an estimated increase in outlier payments of 0.5 percent (from our current estimate of FY 2019 outlier payments of approximately 4.6 percent to 5.1 percent projected for FY 2020 based on the FY 2018 MedPAR data used for this proposed rule calculated for purposes of this impact analysis). There are also interactive effects among the various factors comprising the payment system that we are not able to isolate, which contribute to our estimate of the proposed changes in payments per discharge from FY 2019 and FY 2020 in Column 8.

Overall payments to hospitals paid under the IPPS due to the proposed applicable percentage increase and proposed changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 3.5 percent for FY 2020. Hospitals in urban areas would experience a 3.5 percent increase in payments per discharge in FY 2020 compared to FY 2019. Hospital payments per discharge in rural areas are estimated to increase by 3.6 percent in FY 2020.

3. Impact Analysis of Table II

Table II below presents the projected impact of the proposed changes for FY 2020 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2019 with the estimated proposed average payments per discharge for FY 2020, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 8 of Table I.

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2020 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2019 payment per discharge (2)	Estimated proposed average FY 2020 payment per discharge (3)	Proposed FY 2020 changes (4)
All Hospitals	3,242	12,722	13,169	3.5
By Geographic Location:				
Urban hospitals	2,476	13,083	13,542	3.5
Large urban areas	1,268	13,512	13,965	3.4
Other urban areas	1,208	12,695	13,161	3.7
Rural hospitals	766	9,507	9,850	3.6
Bed Size (Urban):				
0–99 beds	643	10,365	10,742	3.6
100–199 beds	759	10,799	11,166	3.4
200–299 beds	431	11,908	12,312	3.4
300–499 beds	424	13,186	13,657	3.6
500 or more beds	219	16,176	16,753	3.6
Bed Size (Rural):				
0–49 beds	302	8,138	8,538	4.9
50–99 beds	272	9,070	9,397	3.6
100–149 beds	108	9,396	9,747	3.7
150–199 beds	45	10,063	10,390	3.2
200 or more beds	39	10,995	11,322	3
Urban by Region:				
New England	112	14,419	14,659	1.7
Middle Atlantic	307	14,637	15,087	3.1
South Atlantic	399	11,666	12,077	3.5
East North Central	386	12,317	12,756	3.6
East South Central	147	10,956	11,448	4.5
West North Central	157	12,618	13,145	4.2
West South Central	375	12,087	12,511	3.5
Mountain	169	13,474	13,882	3
Pacific	374	16,369	17,036	4.1
Puerto Rico	50	10,011	11,372	13.6
Rural by Region:				
New England	20	13,020	13,315	2.3
Middle Atlantic	53	9,462	9,752	3.1
South Atlantic	120	8,832	9,146	3.6
East North Central	114	9,728	10,054	3.4
East South Central	150	8,378	8,742	4.3
West North Central	93	10,140	10,479	3.3
West South Central	142	8,346	8,718	4.5
Mountain	50	11,616	12,004	3.3
Pacific	24	13,038	13,511	3.6
By Payment Classification:				
Urban hospitals	2,188	12,808	13,259	3.5
Large urban areas	1,283	13,500	13,953	3.4
Other urban areas	905	11,827	12,276	3.8
Rural areas	1,054	12,489	12,927	3.5
Teaching Status:				
Nonteaching	2,127	10,470	10,844	3.6
Fewer than 100 residents	865	12,053	12,476	3.5
100 or more residents	250	18,611	19,257	3.5
Urban DSH:				
Non-DSH	538	10,979	11,389	3.7
100 or more beds	1,393	13,225	13,687	3.5
Less than 100 beds	352	9,704	10,035	3.4
Rural DSH:				
SCH	256	10,588	10,908	3
RRC	442	13,267	13,735	3.5
100 or more beds	31	10,829	11,142	2.9
Less than 100 beds	230	7,737	8,133	5.1
Urban teaching and DSH:				
Both teaching and DSH	776	14,386	14,889	3.5
Teaching and no DSH	84	12,239	12,692	3.7
No teaching and DSH	969	10,835	11,213	3.5
No teaching and no DSH	359	10,155	10,550	3.9
Special Hospital Types:				

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2020 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2019 payment per discharge (2)	Estimated proposed average FY 2020 payment per discharge (3)	Proposed FY 2020 changes (4)
RRC	380	13,332	13,821	3.7
SCH	305	11,467	11,819	3.1
MDH	149	8,369	8,702	4
SCH and RRC	143	11,736	12,080	2.9
MDH and RRC	17	10,287	10,553	2.6
Type of Ownership:				
Voluntary	1,893	12,819	13,266	3.5
Proprietary	852	11,212	11,618	3.6
Government	496	14,213	14,720	3.6
Medicare Utilization as a Percent of Inpatient Days:				
0–25	596	15,799	16,342	3.4
25–50	2,122	12,520	12,966	3.6
50–65	414	10,126	10,455	3.2
Over 65	73	7,473	8,010	7.2
FY 2020 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	957	12,966	13,401	3.4
Non-Reclassified Hospitals	2,285	12,583	13,038	3.6
Urban Hospitals Reclassified	679	13,560	14,013	3.3
Urban Non-reclassified Hospitals	1,753	12,808	13,271	3.6
Rural Hospitals Reclassified Full Year	278	9,767	10,100	3.4
Rural Non-reclassified Hospitals Full Year	441	9,158	9,519	4
All Section 401 Reclassified Hospitals:	335	14,090	14,579	3.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	9,292	9,606	3.4

H. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. As noted in section I.G. of this regulatory impact analysis, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain proposed changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes using that payment simulation model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other proposed changes are discussed in this section.

1. Effects of Proposed Policies Relating to New Medical Service and Technology Add-On Payments

a. Proposed FY 2020 Status of Technologies Approved for FY 2019 New Technology Add-On Payments

In section II.H. of the preamble to this proposed rule, we discuss 17 technologies for which we received applications for add-on payments for new medical services and technologies for FY 2020, as well as the status of the new technologies that were approved to receive new technology add-on payments in FY 2019. We note that one applicant withdrew its application prior to the issuance of this proposed rule. As explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.H.5. of the preamble of this proposed rule, we have not yet determined whether any of the 17 technologies discussed in that section will meet the specified criteria for new technology add-on payments for FY 2020. Consequently, it is premature to estimate the potential payment impact of these 17 technologies for any potential new technology add-on payments for FY 2020. We note that if any of the 17 technologies are found to be eligible for new technology add-on payments for FY 2020, in the FY 2020 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2020.

In section II.H.4. of the preamble of this proposed rule, we are proposing to discontinue new technology add-on payments for Defitelio® (Defibrotide), Ustekinumab (Stelara®) and Bezlotoxumab (Zinplava™) for FY 2020 because these technologies will have been on the U.S. market for 3 years. We also are proposing to continue to make new technology add-on payments for AndexXa™, the AQUABEAM System (Aquablation), GIAPREZA™, KYMRIAH® and YESCARTA®, the remedē® System, the Sentinel® Cerebral Protection System, VABOMERE™, VYXEOS™, and ZEMDRI™ in FY 2020 because these technologies would still be considered new for purposes of new technology add-on payments. Under our proposed change to the calculation of the new technology add-on payments, the new technology add-on payment for each case would be limited to the lesser of: (1) 65 Percent of the costs of the new technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case. Because it is difficult to predict the actual new technology add-on payment for each case, our estimates below are based on the increase in new technology add-on payments for FY 2020 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. The following are estimates for FY 2020 for the 9 technologies for which we are proposing to continue to make new technology add-on payments in FY 2020:

- Based on the applicant's estimate from FY 2019, we currently estimate that new technology add-on payments for AndexXa™ would increase overall FY 2020 payments by $98,755,313 (maximum add-on payment of $18,281.25 * 5,402 patients).
- Based on the applicant's estimate from FY 2019, we currently estimate that new technology add-on payments for the AQUABEAM System (Aquablation) would increase overall FY 2020 payments by $677,625 (maximum add-on payment of $1,625 * 417 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new

technology add-on payments for GIAPREZA™ would increase overall FY 2020 payments by $11,173,500 (maximum add-on payment of $1,950 * 5,730 patients).

- Based on both applicants' estimates of the average cost for an administered dose for FY 2019, we currently estimate that new technology add-on payments for KYMRIAH® and YESCARTA® would increase overall FY 2020 payments by $93,585,700 (maximum add-on payment of $242,450 * 386 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for Sentinel® Cerebral Protection System would increase overall FY 2020 payments by $11,830,000 (maximum add-on payment of $1,820 * 6,500 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for the remedē® System would increase overall FY 2020 payments by $1,794,000 (maximum add-on payment of $22,425 * 80 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for VABOMERE™ would increase overall FY 2020 payments by $19,084,666 (maximum add-on payment of $7,207.20 * 2,648 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for VYXEOS™ would increase overall FY 2020 payments by $45,458,400 (maximum add-on payment of $47,352.50 * 960 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for ZEMDRI™ would increase overall FY 2020 payments by $8,848,125 (maximum add-on payment of $3,539.25 * 2,500 patients).

b. Proposed Alternative Inpatient New Technology Add-On Payment Pathway for Transformative New Devices

In section II.H.8. of the preamble of this proposed rule, we discuss our proposed alternative inpatient new technology add-on payment pathway for certain new technologies. Specifically, we are proposing that, for applications received for IPPS new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of the FDA's Breakthrough Devices Program and received FDA market authorization, such a device would be considered new and not substantially similar to an existing technology for purposes of new technology add-on payment under the IPPS. We also are proposing that the medical device would not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

Given the relatively recent introduction of the Breakthrough Devices Program, there have not been any medical devices that were part of the Breakthrough Devices Program and received FDA market authorization, and that applied for a new technology add-on payment under the IPPS and were not approved. If all of the future new transformative medical devices that would have applied for new technology add-on payments would have been approved under the existing criteria, this proposal has no impact. To the extent that there are future medical devices that are the subject of applications for new technology add-on payments, and those applications would have been denied under the current new technology add-on payment criteria, this proposal is a cost, but that cost is not estimable. We also note that as this proposal, if finalized, would be effective beginning with new technology add-on payment applications for FY 2021, there would be no impact of this proposal in FY 2020.

c. Proposed Changes to the Calculation of the Inpatient New Technology Add-On Payment

In section II.H.9. of the preamble of this proposed rule, we discuss our proposal to modify the current new technology add-on payment mechanism to increase the amount of the maximum add-on payment amount to 65 percent. Specifically, we are proposing that if the costs of a discharge (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare would make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. Unless the discharge qualifies for an outlier payment, the additional Medicare payment would be limited to the full MS–DRG payment plus 65 percent of the estimated costs of the new technology or medical service.

As discussed above, it is premature to estimate the potential payment impact for any potential new technology add-on payments for FY 2020 of the 17 technologies discussed in section II.H.5. of the preamble of this proposed rule because we have not yet determined whether any of these technologies will meet the specified criteria for new technology add-on payments for FY 2020. However, for purposes of estimating the impact of our proposed changes to the calculation of the inpatient new technology add-on payment, we are including the estimated increase in FY 2020 new technology add-on payments if we determine that all 17 of the technologies discussed in that section meet the specified criteria for new technology add-on payments for FY 2020. We estimate that if we finalize our proposals for the 9 technologies for which we are proposing to continue to make new technology add-on payments in FY 2020 and if we determine that all 17 of the FY 2020 new technology add-on payment applications meet the specified criteria for new technology add-on payments for FY 2020, proposed changes to the calculation of the inpatient new technology add-on payment, if finalized, would increase IPPS spending by approximately $110 million in FY 2020.

2. Effects of Proposed Changes to MS–DRGs Subject to the Postacute Care Transfer Policy and the MS–DRG Special Payment Policy

In section IV.A. of the preamble of this proposed rule, we discuss our proposed changes to the list of MS–DRGs subject to the postacute care transfer policy and the MS–DRG special payment policy for FY 2020. As reflected in Table 5 listed in section VI. of the Addendum to this proposed rule (which is available via the internet on the CMS website), using criteria set forth in regulations at 42 CFR 412.4, we evaluated MS–DRG charge, discharge, and transfer data to determine which proposed new or revised MS–DRGs would qualify for the postacute care transfer and MS–DRG special payment policies. As a result of our proposals to revise the MS–DRG classifications for FY 2020, which are discussed in section II.F. of the preamble of this proposed rule, we are proposing to remove two MS–DRGs from the list of MS–DRGs that would be subject to the postacute care transfer policy and the MS–DRG special payment policy. Column 2 of Table I in this Appendix A shows the effects of the proposed changes to the MS–DRGs and the proposed relative payment weights and the application of the proposed recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate DRG classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The analysis and methods for determining the changes due to the MS–DRGs and relative payment weights account for and include changes as a result of the proposed changes to the MS–DRGs subject to the MS–DRG postacute care transfer and MS–DRG special payment policies. We refer readers to section I.G. of this Appendix A for a detailed discussion of payment impacts due to the proposed MS–DRG reclassification policies for FY 2020.

3. Effects of Low-Volume Hospital Payment Adjustment Policy

In section IV.D. of the preamble of this proposed rule, we discuss the low-volume hospital payment policy for FY 2020. Specifically, to qualify for the low-volume hospital payment adjustment, a hospital must be located more than 15 road miles from another subsection (d) hospital and have less than 3,800 total discharges during the fiscal year based on the hospital's most recently submitted cost report. The low-volume hospital payment adjustment is a per-discharge payment adjustment calculated as follows:

- 25 percent for low-volume hospitals with 500 or fewer total discharges;
- (95/330) − (number of total discharges/13,200) for low-volume hospitals with fewer than 3,800 discharges but more than 500 discharges.

Based upon the best available data at this time, we estimate payments made under the low-volume hospital payment adjustment policy would increase Medicare payments by $25 million in FY 2020 as compared to FY 2019. More specifically, in FY 2020, we estimate that 588 providers would receive approximately $439 million compared to our estimate of 588 providers receiving approximately $414 million in FY 2019. These payment estimates were determined by identifying providers that, based on the best available data, qualify in FY 2019 (that is, are located at least 15 miles from the nearest

subsection (d) hospital and have less than 3,800 total discharges).

4. Effects of the Proposed Changes to Medicare DSH and Uncompensated Care Payments for FY 2020

As discussed in section IV.F. of the preamble of this proposed rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals and any additional statutory adjustment (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this proposed rule, we are proposing to establish the amount to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2020 is $8,488,517,726.22. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a proposed Factor 2 of 67.14 percent. For FY 2019, the amount available to be distributed for uncompensated care was $8,272,872,447.22, or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 67.51 percent. To calculate Factor 3 for FY 2020, we are proposing to use hospitals' FY 2015 cost reports from the HCRIS database, as updated through February 15, 2019, Medicaid days from hospitals' FY 2013 cost reports from the same extract of HCRIS, and SSI days from the FY 2017 SSI ratios. For each eligible hospital, with the exception of Puerto Rico hospitals and Indian Health Service and Tribal hospitals, we calculated a Factor 3 using information on uncompensated care costs from cost reports for FY 2015. To calculate Factor 3 for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, we used data regarding low-income insured days for FY 2013. For a complete discussion of the proposed methodology for calculating Factor 3, we refer readers to section IV.F.4. of the preamble of this proposed rule.

To estimate the impact of the combined effect of proposed changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare uncompensated care payments, we compared total uncompensated care payments estimated in the FY 2019 IPPS/LTCH PPS final rule to total uncompensated care payments estimated in this FY 2020 IPPS/LTCH PPS proposed rule. For FY 2019, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 67.51 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2019 IPPS/LTCH PPS final rule. For FY 2020, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a proposed Factor 2 of 67.14 percent and multiplied by a Factor 3 calculated using the proposed methodology described previously.

Our analysis included 2,430 hospitals that are projected to be eligible for DSH in FY 2020. It did not include hospitals that terminated their participation from the Medicare program as of January 1, 2019, Maryland hospitals, new hospitals, MDHs, and SCHs that are expected to be paid based on their hospital-specific rates. The 29 hospitals participating in the Rural Community Hospital Demonstration Program were excluded from this analysis, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In addition, the data from merged or acquired hospitals were combined under the surviving hospital's CMS certification number (CCN), and the nonsurviving CCN was excluded from the analysis. The estimated impact of the proposed changes in Factors 1, 2, and 3 on uncompensated care payments across all hospitals projected to be eligible for DSH payments in FY 2020, by hospital characteristic, is presented in the following table.

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Modeled Uncompensated Care Payments for Estimated FY 2020 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* - from FY 2019 to FY 2020

	Number of Estimated DSHs (1)	FY 2019 Final Rule Estimated Uncompen-sated Care Payments ($ in millions) (2)	FY 2020 Proposed Rule Estimated Uncompen-sated Care Payments ($ in millions) (3)	Dollar Difference: FY 2019 - FY 2020 ($ in millions) (4)	Percent Change** (5)
Total	**2,430**	**$8,273**	**$8,489**	**$216**	**2.61**
By Geographic Location					
Urban Hospitals	1,929	$7,806	$7,914	$109	1.39
Large Urban Areas	976	$4,365	$4,650	$284	6.51
Other Urban Areas	953	$3,440	$3,265	-$176	-5.11
Rural Hospitals	501	$467	$574	$107	22.90
Bed Size (Urban)					
0 to 99 Beds	340	$258	$325	$67	25.79
100 to 249 Beds	842	$1,892	$2,027	$135	7.15
250+ Beds	747	$5,656	$5,563	-$93	-1.65
Bed Size (Rural)					
0 to 99 Beds	371	$229	$300	$71	31.08
100 to 249 Beds	117	$195	$225	$30	15.35
250+ Beds	13	$43	$49	$6	13.52
Urban by Region					
New England	90	$279	$260	-$19	-6.92
Middle Atlantic	242	$1,058	$1,107	$49	4.64
South Atlantic	309	$1,769	$1,898	$130	7.33
East North Central	321	$1,010	$862	-$148	-14.64
East South Central	132	$477	$478	$1	0.14
West North Central	102	$386	$386	-$1	-0.17
West South Central	245	$1,423	$1,744	$320	22.52
Mountain	125	$401	$380	-$21	-5.31
Pacific	321	$899	$688	-$211	-23.45
Puerto Rico	42	$102	$111	$9	8.57

Modeled Uncompensated Care Payments for Estimated FY 2020 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* - from FY 2019 to FY 2020

	Number of Estimated DSHs (1)	FY 2019 Final Rule Estimated Uncompen-sated Care Payments ($ in millions) (2)	FY 2020 Proposed Rule Estimated Uncompen-sated Care Payments ($ in millions) (3)	Dollar Difference: FY 2019 - FY 2020 ($ in millions) (4)	Percent Change** (5)
Rural by Region					
New England	9	$17	$16	-$1	-4.89
Middle Atlantic	24	$22	$22	0	0.64
South Atlantic	90	$116	$151	$35	30.44
East North Central	70	$56	$63	$7	12.41
East South Central	132	$106	$116	$10	9.55
West North Central	35	$22	$39	$17	75.84
West South Central	109	$102	$135	$33	32.81
Mountain	25	$22	$25	$3	11.95
Pacific	7	$5	$7	$2	50.40
By Payment Classification					
Urban Hospitals	1,694	$6,564	$6,780	$216	3.29
Large Urban Areas	987	$4,377	$4,659	$282	6.44
Other Urban Areas	707	$2,187	$2,122	-$66	-3.01
Rural Hospitals	736	$1,709	$1,708	0	-0.01
Teaching Status					
Nonteaching	1,468	$2,514	$2,700	$185	7.37
Fewer than 100 residents	716	$2,812	$2,770	-$43	-1.52
100 or more residents	246	$2,946	$3,019	$73	2.48
Type of Ownership					
Voluntary	1,448	$4,898	$4,648	-$250	-5.11
Proprietary	600	$1,270	$1,310	$40	3.12
Government	382	$2,105	$2,531	$426	20.26
Medicare Utilization Percent***					
0 to 25	505	$2,956	$3,165	$209	7.07
25 to 50	1,661	$5,086	$5,052	-$34	-0.67
50 to 65	227	$223	$261	$38	17.14

Modeled Uncompensated Care Payments for Estimated FY 2020 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* - from FY 2019 to FY 2020

	Number of Estimated DSHs (1)	FY 2019 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2020 Proposed Rule Estimated Uncompensated Care Payments ($ in millions) (3)	Dollar Difference: FY 2019 - FY 2020 ($ in millions) (4)	Percent Change** (5)
Greater than 65	35	$8	$10	$2	27.08

Source: Dobson | DaVanzo analysis of 2013-2015 Hospital Cost Reports.

*Dollar uncompensated care payments calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, uncompensated care payments are estimated to be $8,273 million in FY 2019 and $8,489 million in FY 2020.

** Percentage change is determined as the difference between Medicare uncompensated care payments modeled for this FY 2020 IPPS/LTCH PPS proposed rule (column 3) and Medicare uncompensated care payments modeled for the FY 2019 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare uncompensated care payments modeled for the FY 2019 IPPS/LTCH PPS final rule correction notice (column 2) times 100 percent.

***Hospitals with missing or unknown Medicare utilization are not shown in table.

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Proposed changes in projected FY 2020 uncompensated care payments from payments in FY 2019 are driven by a proposed increase in Factor 1 and a proposed decrease in Factor 2, as well as by a decrease in the number of hospitals projected to be eligible to receive DSH in FY 2020 relative to FY 2019. Proposed Factor 1 has increased from $12.254 billion to $12.643 billion, and the proposed percent change in the percent of individuals who are uninsured (Factor 2) has decreased from 67.51 percent to 67.14 percent. Based on the proposed changes in these two factors, the impact analysis found that, across all projected DSH eligible hospitals, proposed FY 2020 uncompensated care payments are estimated at approximately $8.489 billion, or a proposed increase of approximately 2.61 percent from FY 2019 uncompensated care payments (approximately $8.273 billion). While these proposed changes would result in a net increase in the amount available to be distributed in uncompensated care payments, the projected payment increases vary by hospital type. This redistribution of uncompensated care payments is caused by proposed changes in Factor 3. As seen in the above table, percent increases smaller than 2.61 percent indicate that hospitals within the specified category are projected to experience a smaller increase in uncompensated care payments, on average, compared to the universe of projected FY 2020 DSH hospitals. Conversely, percent increases that are greater than 2.61 percent indicate a hospital type is projected to have a larger increase than the overall average. The variation in the distribution of payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported in the Worksheet S–10, or number of Medicaid days and SSI days for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, used in the Factor 3 computation.

Rural hospitals, in general, are projected to experience significantly larger increases in uncompensated care payments than their urban counterparts. Overall, rural hospitals are projected to receive a 22.90 percent increase in uncompensated care payments, while urban hospitals are projected to receive a 1.39 percent increase in uncompensated care payments.

By bed size, smaller hospitals are projected to receive larger increases in uncompensated care payments than larger hospitals, in both rural and urban settings. Rural hospitals with 0–99 beds are projected to receive a 31.08 percent payment increase, rural hospitals with 100–249 beds are projected to receive a 15.35 percent increase, and larger rural hospitals with 250+ beds are projected to receive a 13.52 percent payment increase. These increases for rural hospitals are all greater than the overall hospital average. This trend is also generally true for urban hospitals, with the smallest urban hospitals (0–99 beds) projected to receive an increase in uncompensated care payments of 25.79 percent, and urban hospitals with 100–249 beds projected to receive an increase of 7.15 percent, both of which are greater than the overall average. Larger urban hospitals with 250+ beds are projected to receive a 1.65 percent decrease in uncompensated care payments.

By region, rural hospitals are expected to receive a wide range of payment increases, except for those in New England, which are projected to receive a decrease in uncompensated care payments. Rural hospitals in the South Atlantic Region are expected to receive a larger than average increase in uncompensated care payments, as are rural hospitals in the West South Central, West North Central, East South Central, East North Central, Mountain, and Pacific Regions. Rural hospitals in the Middle Atlantic Region are projected to receive smaller than average payment increases. Regionally, urban hospitals are projected to receive a more varied range of payment changes. Urban hospitals in the New England, East North Central, West North Central, Mountain and Pacific Regions are projected to receive decreases in uncompensated care payments. Smaller than average increases in uncompensated care payments are projected in the East South Central Region, while hospitals in the Middle Atlantic, South Atlantic, and West South Central Regions and in Puerto Rico are

projected to receive larger than average increases in uncompensated care payments.

Nonteaching hospitals are projected to receive a larger than average payment increase of 7.37 percent. Teaching hospitals with fewer than 100 residents are projected to receive a payment decrease of 1.52 percent, while those teaching hospitals with 100+ residents have a projected payment increase of 2.48 percent, slightly lower than the overall average. Government hospitals are projected to receive a larger than average increase of 20.26 percent, while proprietary hospitals are projected to receive a payment increase slightly above the average at 3.12 percent. Voluntary hospitals are expected to receive a payment decrease of 5.11 percent. Hospitals with 0 to 25 percent Medicare utilization, or above 50 percent Medicare utilization, are projected to receive increases in uncompensated care payments. Hospitals with 25–50 percent Medicare utilization are projected to receive a slight decrease in uncompensated care payments.

As discussed in section IV.F. of the preamble of this proposed rule, an alternative methodology that we are considering for FY 2020 would be to use FY 2017 Worksheet S–10 data instead of FY 2015 Worksheet S–10 data to determine Factor 3. Our analysis for this alternative methodology included 2,433 hospitals that would be projected to be eligible for DSH in FY 2020 under this approach. We note that the 3 hospital difference compared to the proposed methodology is due to a difference in the new hospital definition under the alternative methodology. (CCN established on or after October 1, 2017, would be considered new.) The estimated impact of the proposed changes in Factors 1 and 2 and the alternative methodology for determining Factor 3 on uncompensated care payments across all hospitals projected to be eligible for DSH payments in FY 2020 is presented in the following table.

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Alternative Modeled Uncompensated Care Payments for Estimated FY 2020 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* from FY 2019 to FY 2020					
	Number of Estimated DSHs	FY 2019 Final Rule Estimated Uncompensated Care Payments ($ in Millions)	FY 2020 Proposed Rule Estimated Uncompensated Care Payments ($ in Millions)	Dollar Difference: FY 2019 - FY 2020 (in Millions)	Percent Change**
Total	**2,443**	**$8,273**	**$8,489**	**$216**	**2.61**
By Geographic Location					
Urban Hospitals	1,940	$7,806	$7,965	$159	2.04
Large Urban Areas	982	$4,365	$4,644	$278	6.37
Other Urban Areas	958	$3,440	$3,321	-$119	-3.45
Rural Hospitals	503	$467	$523	$56	12.04
Bed Size (Urban)					
0 to 99 Beds	348	$258	$331	$73	28.14
100 to 249 Beds	845	$1,892	$1,944	$53	2.78
250+ Beds	747	$5,656	$5,690	$34	0.61
Bed Size (Rural)					
0 to 99 Beds	373	$229	$266	$37	15.95
100 to 249 Beds	117	$195	$206	$11	5.54
250+ Beds	13	$43	$52	$9	20.76
Urban by Region					
New England	90	$279	$256	-$23	-8.32
Middle Atlantic	243	$1,058	$1,058	-$1	-0.05
South Atlantic	312	$1,769	$1,998	$229	12.97
East North Central	323	$1,010	$873	-$137	-13.58
East South Central	132	$477	$505	$28	5.82
West North Central	102	$386	$400	$14	3.56
West South Central	246	$1,423	$1,687	$264	18.56
Mountain	127	$401	$349	-$52	-13.05
Pacific	323	$899	$728	-$171	-19.03
Puerto Rico	42	$102	$111	$9	8.57
Rural by Region					
New England	9	$17	$15	-$2	-10.27
Middle Atlantic	24	$22	$16	-$6	-25.47
South Atlantic	91	$116	$144	$28	24.01
East North Central	70	$56	$61	$5	8.84
East South Central	132	$106	$109	$3	2.79
West North Central	35	$22	$36	$14	62.92

Alternative Modeled Uncompensated Care Payments for Estimated FY 2020 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* from FY 2019 to FY 2020

	Number of Estimated DSHs	FY 2019 Final Rule Estimated Uncompensated Care Payments ($ in Millions)	FY 2020 Proposed Rule Estimated Uncompensated Care Payments ($ in Millions)	Dollar Difference: FY 2019 - FY 2020 (in Millions)	Percent Change**
West South Central	110	$102	$114	$13	12.41
Mountain	25	$22	$21	-$1	-3.99
Pacific	7	$5	$7	$2	41.47
By Payment Classification					
Urban Hospitals	1,706	$6,564	$6,826	$262	3.99
Large Urban Areas	993	$4,377	$4,654	$277	6.33
Other Urban Areas	713	$2,187	$2,172	-$15	-0.70
Rural Hospitals	737	$1,709	$1,662	-$46	-2.70
Teaching Status					
Nonteaching	1,481	$2,514	$2,641	$126	5.03
Fewer than 100 residents	716	$2,812	$2,875	$62	2.22
100 or more residents	246	$2,946	$2,973	$27	0.91
Type of Ownership					
Voluntary	1,454	$4,898	$4,760	-$138	-2.81
Proprietary	606	$1,270	$1,273	$3	0.23
Government	383	$2,105	$2,455	$350	16.65
Medicare Utilization Percent***					
0 to 25	506	$2,956	$3,101	$145	4.89
25 to 50	1,666	$5,086	$5,119	$33	0.64
50 to 65	228	$223	$252	$29	12.90
Greater than 65	36	$8	$9	$2	26.26

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As seen in the above table for the alternative methodology under consideration, rural hospitals, in general, are projected to experience larger increases in uncompensated care payments than their urban counterparts. Overall, rural hospitals are projected to receive a 12.04 percent increase in uncompensated care payments, while urban hospitals are projected to receive a 2.04 percent increase in uncompensated care payments.

By bed size, smaller hospitals in urban areas are projected to receive significantly larger increases in uncompensated care payments than their larger counterparts. The smallest urban hospitals (0–99 beds) are projected to receive an increase of 28.14 percent in uncompensated care payments, while urban hospitals with 100–249 beds are projected to see an increase of 2.78 percent, and those with 250+ beds are projected to receive a slight increase of 0.61 percent, which is smaller than the overall average uncompensated care payment increase. Conversely, among rural hospitals, the largest rural hospitals (250+ beds) are projected to receive the largest increase in uncompensated care payments at 20.76 percent. Rural hospitals with 100–249 beds are projected to receive an increase of 5.54 percent, and the smallest rural hospitals (0–99 beds) are projected receive an increase of 15.95 percent.

By region, urban hospitals in the New England, Middle Atlantic, East North Central, Mountain and Pacific Regions are projected to receive decreases in uncompensated care payments. Urban hospitals in the South Atlantic, East South Central, West North Central, and West South Central Regions and in Puerto Rico are expected to receive above average uncompensated care payment increases ranging from 3.56 percent to 18.56 percent. Among rural hospitals, those in the New England, Middle Atlantic and Mountain Regions are expected to receive decreases in uncompensated care payments. Rural hospitals in the South Atlantic, East North Central, East South Central, West North Central, West South Central, and Pacific Regions are projected receive varied uncompensated care payment increases, ranging from 2.79 percent to 62.92 percent.

Nonteaching hospitals are projected to receive a larger than average payment increase of 5.03 percent. Teaching hospitals with fewer than 100 residents are projected to receive a payment increase of 2.22 percent, while those teaching hospitals with 100+ residents have a projected payment increase of 0.91 percent, both of which are lower than the overall average. Government hospitals are projected to receive a larger than average increase of 16.65 percent, while proprietary hospitals are projected to receive a payment increase below the average at 0.23 percent. Voluntary hospitals are expected to receive a payment decrease of 2.81 percent. Hospitals with 0 to 25 percent Medicare utilization, or above 50 percent Medicare utilization, are projected to receive higher than average increases in uncompensated care payments. Hospitals with 25 to 50 percent Medicare utilization are projected to receive a lower than average increase in uncompensated care payments of 0.64 percent.

5. Effects of Proposed Reductions Under the Hospital Readmissions Reduction Program for FY 2020

In section IV.G. of the preamble of this proposed rule, we discuss our proposed policies for the FY 2020 Hospital Readmissions Reduction Program. This program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. The table and analysis below illustrate the estimated financial impact of

the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic. As outlined in section IV.G. of the preamble of this proposed rule, hospitals are stratified into quintiles based on the proportion of dual-eligible stays among Medicare fee-for-service (FFS) and managed care stays between July 1, 2014 and June 30, 2017 (that is, the FY 2019 Hospital Readmissions Reduction Program's performance period). Hospitals' excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied in the payment adjustment factor calculation to maintain budget neutrality. To analyze the results by hospital characteristic, we used the FY 2019 Hospital IPPS Proposed Rule Impact File.

These analyses include 3,062 non-Maryland hospitals eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between July 1, 2014 and June 30, 2017. The second column in the table indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals).

The third column in the table indicates the percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 82.26 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 88.60 percent of eligible hospitals with fewer than 100 residents and 93.95 percent of eligible hospitals with 100 or more residents are expected to be penalized.

The fourth column in the table estimates the financial impact on hospitals by hospital characteristics. The table shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between October 1, 2016 and September 30, 2017 (FY 2017). For example, the penalty as a share of payments for urban hospitals is 0.67 percent. This means that total penalties for all urban hospitals are 0.67 percent of total payments for urban hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals within the characteristic when comparing the financial impact of the program on different groups of hospitals.

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Proxy Percentage of Hospitals Penalized and Penalty as Share of Payments for FY 2020 Hospital Readmissions Reduction Program by Hospital Characteristic				
Hospital Characteristic	**Number of Eligible Hospitals[a]**	**Number of Penalized Hospitals[b]**	**Percentage of Hospitals Penalized[c] (%)**	**Penalty as a share of payments[d] (%)**
All Hospitals	3,062	2,599	84.88	0.67
Geographic Location[e] (n= 3,062)				
Urban hospitals	2,297	1,983	86.33	0.67
1-99 beds	534	377	70.60	0.90
100-199 beds	714	649	90.90	0.79
200-299 beds	417	378	90.65	0.77
300-399 beds	275	253	92.00	0.68
400-499 beds	144	130	90.28	0.54
500 or more beds	213	196	92.02	0.55
Rural hospitals	765	616	80.52	0.69
1-49 beds	285	197	69.12	0.63
50-99 beds	282	242	85.82	0.62
100-149 beds	115	104	90.43	0.72
150-199 beds	44	35	79.55	0.64
200 or more beds	39	38	97.44	0.81
Teaching Status[f] (n= 3,062)				
Non-teaching	2,007	1,651	82.26	0.78
Teaching, fewer than 100 Residents	807	715	88.60	0.68
Teaching,100 or more Residents	248	233	93.95	0.50
Ownership Type (n= 3,043)				
Government	476	399	83.82	0.51
Proprietary	748	619	82.75	1.01
Voluntary	1,819	1,573	86.48	0.63
Safety-net Status[g] (n= 3,062)				
Safety-net hospitals	614	531	86.48	0.58
Non-safety-net Hospitals	2,448	2,068	84.48	0.70

Disproportionate Share Hospital (DSH) Patient Percentage[h] (n= 3,062)				
0-24	1,221	997	81.65	0.76
25-49	1,485	1,293	87.07	0.63
50-64	189	171	90.48	0.63
65 and over	167	138	82.63	0.60
Medicare Cost Report (MCR) Percent[i] (n= 3,048)				
0-24	432	364	84.26	0.46
25-49	2,087	1,802	86.34	0.68
50-64	467	381	81.58	0.93
65 and over	62	42	67.74	0.90
Region (n= 3,062)				
New England	129	114	88.37	0.85
Middle Atlantic	352	320	90.91	0.85
South Atlantic	509	461	90.57	0.75
East North Central	482	421	87.34	0.59
East South Central	289	253	87.54	0.86
West North Central	246	193	78.46	0.43
West South Central	474	384	81.01	0.65
Mountain	217	163	75.12	0.55
Pacific	364	290	79.67	0.46

Source: The table results are based on the proxy FY 2020 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. The proxy FY 2020 payment adjustment factors are based on discharges between July 1, 2014 and June 30, 2017 (the FY 2019 Hospital Readmissions Reduction Program performance period). Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals and hospitals that are not open as of the October 2018 public reporting open hospital list since these hospitals are not eligible for a penalty under the program. Hospitals are stratified into quintiles based on the proportion of Medicare FFS and managed care dual-eligible stays for the 3-year performance period. Hospital characteristics are from the FY 2019 Hospital IPPS Proposed Rule Impact File.

Note: After the release of the FY 2019 IPPS/LTCH PPS final rule, it was determined that the neutrality modifier was not applied in the calculation of the penalty as a share of payments presented in the FY 2019 IPPS/LTCH PPS final rule table (83 FR 41755 through 41756). This error only affected the penalty as a share of payments by hospital characteristics (that is, the result for all hospitals was not impacted). The penalty as share of payments results in the FY 2019 IPPS/LTCH PPS final rule table were slightly higher than the corrected results. The table above includes the corrected values for the penalty as a share of payments.

Footnotes:

[a] This column is the number of applicable hospitals within the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an proxy payment adjustment factor less than 1) within the characteristic.

[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.

[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. MedPAR data from October 1, 2016 through September 30, 2017 (FY 2017) are used to calculate the total base operating DRG payments.

[e] The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. All hospitals had information for: geographic location, bed size by geographic region, teaching status, safety-net status, DSH patient percentage, and region (n=3,062). Not all hospitals had data for ownership type (n=3,043; missing=19) and MCR percent (n=3,048; missing=14).

[f] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS (TCHOP) greater than zero.

[g] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[h] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[i] MCR percent is the percentage of total inpatient stays from Medicare patients.

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6. Effects of Proposed Changes Under the FY 2020 Hospital Value-Based Purchasing (VBP) Program

In section IV.H. of the preamble of this proposed rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2020 through a reduction to the FY 2020 base operating DRG payment amount for the discharge for the hospital for such fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2020 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary.

In section IV.H.1.b. of the preamble of this proposed rule, we estimate the available pool of funds for value-based incentive payments in the FY 2020 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, would be 2.00 percent of base operating DRG payments, or a total of approximately $1.9 billion. This estimated available pool for FY 2020 is based on the historical pool of hospitals that were eligible to participate in the FY 2019 program year and the payment information from the December 2018 update to the FY 2018 MedPAR file.

The proposed estimated impacts of the FY 2020 program year by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2019 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the December 2018 update to the FY 2018 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the internet on the CMS website).

The impact analysis shows that, for the FY 2020 program year, the number of hospitals that would receive an increase in their base operating DRG payment amount is higher than the number of hospitals that would receive a decrease. On average, urban hospitals in the West North Central region and rural hospitals in the Mountain region would have the highest positive percent change in base operating DRG. Urban Middle Atlantic, Urban East South Central, and Urban West South Central regions would experience an average decrease in base operating DRG. All other regions, both urban and rural, would experience an average increase in base operating DRG.

As DSH patient percentage increases, the average percent change in base operating DRG would tend to decrease. With respect to hospitals' Medicare utilization as a percent of inpatient days (MCR), as the MCR percent increases, the average percent change in base operating DRG would increase. On average, teaching hospitals would have a decrease in base operating DRG while non-teaching hospitals would have an increase in base operating DRG.

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Impact Analysis of Adjustments to Base Operating DRG Payment Amounts Resulting from the FY 2020 Hospital VBP Program			
		Number of Hospitals	**Average Net Percentage Payment Adjustment**
BY GEOGRAPHIC LOCATION:			
	All Hospitals	**2,786**	**0.164**
	Large Urban	1,107	0.076
	Other Urban	1,025	0.087
	Rural Area	654	0.436
	Urban hospitals	***2,132***	***0.081***
	0-99 beds	377	0.464
	100-199 beds	705	0.148
	200-299 beds	421	-0.040
	300-499 beds	412	-0.139
	500 or more beds	217	-0.151
	Rural hospitals	***654***	***0.436***
	0-49 beds	204	0.600
	50-99 beds	264	0.464
	100-149 beds	103	0.369
	150-199 beds	45	0.125
	200 or more beds	38	-0.090
BY REGION:			
	Urban By Region	**2,132**	**0.081**
	New England	105	0.069
	Middle Atlantic	282	-0.030
	South Atlantic	378	0.012
	East North Central	350	0.157
	East South Central	129	-0.121
	West North Central	135	0.363
	West South Central	264	-0.014
	Mountain	146	0.107
	Pacific	343	0.202
	Rural By Region	**654**	**0.436**
	New England	19	0.597
	Middle Atlantic	49	0.364
	South Atlantic	104	0.488

Impact Analysis of Adjustments to Base Operating DRG Payment Amounts Resulting from the FY 2020 Hospital VBP Program			
		Number of Hospitals	**Average Net Percentage Payment Adjustment**
	East North Central	109	0.572
	East South Central	121	0.158
	West North Central	80	0.548
	West South Central	101	0.259
	Mountain	47	0.803
	Pacific	24	0.669
By MCR Percent			
	0-25	476	0.083
	25-50	1,949	0.163
	50-65	333	0.281
	Over 65	21	0.351
	Missing	7	-0.021
BY DSH Patient Percentage:			
	0-25	1,051	0.288
	25-50	1,404	0.116
	50-65	173	-0.034
	Over 65	158	-0.011
BY TEACHING STATUS:			
	Non-Teaching	1,732	0.273
	Teaching	1,054	-0.015

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Actual FY 2020 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2020 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2019 program year will be used for the updated impact analysis in the final rule.

7. Effects of Proposed Requirements Under the HAC Reduction Program for FY 2020

In section IV.I. of the preamble of this proposed rule, we discuss proposed requirements for the HAC Reduction Program for FY 2020. In this proposed rule, we are not proposing to remove measures or to adopt any new measures into the HAC Reduction Program.

a. Burden Associated With Validation

We note the burden associated with collecting and submitting data via the NHSN system is captured under a separate OMB control number, 0920–0666, and therefore will not impact our burden estimates.

We discuss the burden hours associated with NHSN HAI validation (43,200 hours over 600 hospitals) in section X.B.7. of the preamble of this proposed rule, and note the burden associated with these requirements is captured in an information collection request currently available for review and comment, OMB control number 0938–1352. We are proposing to update our cost burden to hospitals using a wage plus benefit rate of $37.66 per hour to account for an increase in wage rate used in the last year's PRA package from $18.29 to $18.83. We believe that doubling the hourly wage rate ($18.83 × 2 = $37.66) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $37.66 per hour.

b. The Cumulative Effect of Program Measures and the Scoring Methodology

We are presenting the estimated impact of the FY 2020 HAC Reduction Program on hospitals by hospital characteristic. These FY 2020 HAC Reduction Program results were calculated using the Equal Measure Weights approach finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41486 through 41489). Each hospital's Total HAC Score was calculated as the equally weighted average of the hospital's measure scores. The table below presents the estimated proportion of hospitals in the worst-performing quartile of the Total HAC Scores by hospital characteristic.

Hospitals' CMS PSI 90 Composite measure results are based on Medicare FFS discharges from July 1, 2016 through June 30, 2018 and the recalibrated version 9.0 of the CMS PSI software. Hospitals' measure results for the CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI measures are derived from standardized

infection ratios (SIRs) calculated with hospital surveillance data reported to the NHSN for infections occurring between January 1, 2016 and December 31, 2017.[842]

To analyze the results by hospital characteristic, we used the FY 2019 Hospital IPPS Final Rule Impact File. This table includes 3,184 non-Maryland hospitals with a FY 2020 Total HAC Score—Maryland hospitals and hospitals without a Total HAC Score are excluded from the table. Of these 3,184 hospitals, 3,170 hospitals had information for geographic location with bed size, safety-net status, DSH patient percentages, and teaching status; 3,182 hospitals had information on region; 3,142 hospitals had information for ownership; and 3,155 hospitals had information for MCR percent. The first column presents a breakdown of each characteristic.

The second column in the table indicates the total number of non-Maryland hospitals with an FY 2020 Total HAC Score and available data for each characteristic. For example, with regard to teaching status, 2,092 hospitals are characterized as non-teaching hospitals, 831 hospitals are characterized as teaching hospitals with fewer than 100 residents, and 247 hospitals are characterized as teaching hospitals with at least 100 residents. This only represents a total of 3,170 hospitals because the other 14 hospitals are missing from the FY 2019 Hospital IPPS Final Rule Impact File.

The third column in the table indicates the number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. These hospitals would receive a payment reduction under the FY 2020 HAC Reduction Program. For example, with regard to teaching status, 458 hospitals out of 2,092 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 208 out of 831 hospitals with fewer than 100 residents, and 120 out of 247 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in the table indicates the proportion of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores and thus receive a payment reduction under the FY 2020 HAC Reduction Program. For example, 21.9 percent of the 2,092 hospitals characterized as non-teaching hospitals, 25.0 percent of the 831 teaching hospitals with fewer than 100 residents, and 48.6 percent of the 247 teaching hospitals with 100 or more residents would be subject to a payment reduction.

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[842] Updated FY 2020 data for the CDC NHSN measures (1/1/2017 through 12/31/2018) was not available at the time of publication.

Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2020 HAC Reduction Program by Hospital Characteristic

Hospital Characteristic	Number of Hospitals	Number of Hospitals in the Worst-Performing Quartile[a]	Percent of Hospitals in the Worst-Performing Quartile[b]
Total[c]	**3,184**	**795**	**25.0**
By Geographic Location (n = 3,170)[d]			
Urban hospitals	**2,397**	**634**	**26.4**
1-99 beds	618	123	19.9
100-199 beds	720	177	24.6
200-299 beds	423	130	30.7
300-399 beds	277	83	30.0
400-499 beds	140	42	30.0
500 or more beds	219	79	36.1
Rural hospitals	**773**	**152**	**19.7**
1-49 beds	307	58	18.9
50-99 beds	275	58	21.1
100-149 beds	107	20	18.7
150-199 beds	45	9	20.0
200 or more beds	39	7	17.9
By Safety-Net Status[e] **(n = 3,170)**			
Non-safety net	2,526	570	22.6
Safety-net	644	216	33.5
By DSH Patient Percentage[f] **(n = 3,170)**			
0-24	1,300	273	21.0
25-49	1,488	372	25.0
50-64	195	73	37.4
65 and over	187	68	36.4
By Teaching Status[g] **(n = 3,170)**			
Non-teaching	2,092	458	21.9
Fewer than 100 residents	831	208	25.0
100 or more residents	247	120	48.6
By Ownership[h] **(n = 3,142)**			
Voluntary	1,854	457	24.6

Hospital Characteristic	Number of Hospitals	Number of Hospitals in the Worst-Performing Quartile[a]	Percent of Hospitals in the Worst-Performing Quartile[b]
Total[c]	**3,184**	**795**	**25.0**
Proprietary	800	168	21.0
Government	488	153	31.4
By MCR Percent[i] **(n = 3,155)**			
0-24	558	160	28.7
25-49	2,121	509	24.0
50-64	404	92	22.8
65 and over	72	19	26.4
By Region[j] **(n = 3,182)**			
New England	131	40	30.5
Mid-Atlantic	358	105	29.3
South Atlantic	521	140	26.9
East North Central	493	105	21.3
East South Central	293	69	23.5
West North Central	254	53	20.9
West South Central	511	110	21.5
Mountain	225	56	24.9
Pacific	396	115	29.0

Source: FY 2020 HAC Reduction Program Proposed Rule Results are based on CMS PSI 90 data from July 2016 through June 2018 and CDC CLABSI, CAUTI, SSI, CDI, and MRSA results from January 2016 through December 2017. Hospital Characteristics are based on the FY 2019 Hospital IPPS Final Rule Impact File.

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a FY 2020 Total HAC Score (N = 3,184). Note that not all hospitals have data for all hospital characteristics.

[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, DSH patient percentage, teaching status, and ownership status (n = 3,170).

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH patient percentage.

[f] The DSH patient percentage is equal to the sum of (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[g] A hospital is considered a teaching hospital if it has an Indirect Medical Education (IME) adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for Ownership (n = 3,142)

[i] Not all hospitals had data for MCR percent (n = 3,155).

[j] Not all hospitals had data for Region (n = 3,182)

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8. Effects of Proposed Changes Relating to Critical Access Hospitals (CAHs) as Nonproviders for Direct GME and IME Payment Purposes

In section IV.J.2. of the preamble of this proposed rule, we discuss our proposal to consider CAHs as nonprovider settings for purposes of direct GME and IME payments such that, effective with portions of cost reporting periods beginning October 1, 2019, a hospital may include full-time equivalent (FTE) residents training at a CAH in its FTE count as long as it meets the nonprovider

setting requirements currently included at 42 CFR 413.78(g). We note that we are not proposing to change our policy with respect to CAHs incurring the costs of training residents. That is, a CAH may continue to incur the costs of training residents in an approved residency training program(s) and be paid based on 101 percent of the reasonable costs for these training costs.

We anticipate any impact associated with this proposed change to be negligible. Because IPPS teaching hospitals have caps in place for the number of FTE residents they may claim for direct GME and IME payment purposes, these hospitals could only receive direct GME and IME payments for the FTE residents for which they incur the training costs at CAHs within their existing FTE caps. Allowing IPPS hospitals to claim FTE residents training at CAHs would not mean the hospitals would be able to claim additional FTE residents above their FTE caps. Thus, because no additional funded slots would be created for IPPS hospitals by this proposal, and because CAHs would no longer be claiming and receiving payment for the salary costs of the residents in situations where the CAHs are being treated as nonprovider sites, we believe there is minimal to no impact.

9. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2020

In section IV.K. of the preamble of this proposed rule for FY 2020, we discussed our implementation and budget neutrality methodology for section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, and more recently, by section 15003 of Public Law 114–255, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 15003 of Public Law 114–255 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 10-year extension period (in place of the 5-year extension period required by the Affordable Care Act), beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Specifically, section 15003 of Public Law 114–255 amended section 410A(g)(4) of Public Law 108–173 to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary shall provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital makes an election to discontinue participation. Furthermore, section 15003 of Public Law 114–255 requires that, during the second 5 years of the 10-year extension period, the Secretary shall provide for participation under the demonstration during the second 5 years of the 10-year extension period for hospitals that are not described in subsection 410A(g)(4).

Section 15003 of Public Law 114–255 also requires that no later than 120 days after the enactment of Public Law 114–255 that the Secretary issue a solicitation for applications to select additional hospitals to participate in the demonstration program for the second 5 years of the 10-year extension period so long as the maximum number of 30 hospitals stipulated by Public Law 111–148 is not exceeded. Section 410A(c)(2) requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality).

In the preamble to this FY 2020 IPPS/LTCH PPS proposed rule, we described the terms of participation for the extension period authorized by Public Law 114–255. In the FY 2018 IPPS/LTCH PPS final rule, we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under the demonstration for those among the hospitals that had previously participated and were choosing to participate in the second 5-year extension period. According to our finalized policy, each of these previously participating hospitals began the second 5 years of the 10-year extension period on the date immediately after the date the period of performance under the 5-year extension period ended. Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by Public Law 111–148 elected to continue in the second 5-year extension period, while 13 additional hospitals were selected to participate. One of the hospitals selected from the solicitation in 2017 withdrew from the demonstration program prior to beginning participation on July 1, 2018. Each of the remaining newly participating hospitals began its 5-year period of participation effective with the start of the first cost reporting period on or after October 1, 2017. Thus, 29 hospitals participated in FYs 2018 and 2019, and are scheduled to participate in FY 2020.

In the FY 2018 IPPS/LTCH PPS final rule, we finalized the budget neutrality methodology in accordance with our policies for implementing the demonstration, adopting the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

For this proposed rule, the resulting amount applicable to FY 2020 is $61,970,567, which we are proposing to include in the budget neutrality offset adjustment for FY 2020. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and proposed update factors for cost and payment. If updated data become available prior to the FY 2020 IPPS/LTCH PPS final rule, we will use them to the extent appropriate to estimate the costs of the demonstration program.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the final IPPS rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2013 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 15003 of Public Law 114–255, we will continue this general procedure. Currently, finalized cost reports are now available for the 22 hospitals that completed a cost reporting period beginning in FY 2014 according to the demonstration cost-based payment methodology. The actual costs of the demonstration for this fiscal year as determined from the finalized cost reports fell short of the estimated amount that was finalized in the FY 2014 IPPS/LTCH PPS final rule by $14,932,060.

We note that, for this proposed rule, the amounts identified for the actual costs of the demonstration for FY 2014 (determined from finalized cost reports) is less than the amount that was identified in the final rule for this fiscal year. Therefore, in keeping with previous policy finalized in similar situations when the costs of the demonstration fell short of the amount estimated in the corresponding year's final rule, we will be including this component as a negative adjustment to the budget neutrality offset amount for the current fiscal year.

Therefore, for FY 2020, the total amount that we are proposing to apply to the national IPPS rates is $47,038,507. If updated data become available prior to the FY 2020 IPPS/LTCH PPS final rule, we would use them to the extent appropriate to determine the budget neutrality offset amount for FY 2020. Furthermore, if the needed cost reports are available in time for the FY 2020 IPPS/LTCH PPS final rule, we will also identify the difference between the total cost of the demonstration based on finalized FY 2015 cost reports and the estimate of the costs of the demonstration for that year, and incorporate that amount into the final budget neutrality offset amount for FY 2020.

10. Effects of Proposed Change Relating to CAH Payment for Ambulance Services

In section VI.C.2. of the preamble of this proposed rule, we discuss our proposal to revise the regulations at § 413.70(b)(5) by

adding a new paragraph (D) to state that, effective for cost reporting periods beginning on or after October 1, 2019, payment for ambulance services furnished by a CAH or by an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals either to or from the CAH. Consistent with the existing policy under § 413.70(b)(5)(i)(C), if there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH.

Based on the best data available, assuming no significant change in the volume of CAH ambulance trips and that approximately 5 CAHs may be affected by the specific situation described in our proposal, we estimate Medicare payments will increase by $2 million in FY 2020 as compared to FY 2019.

11. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VI.C.3. of the preamble of this proposed rule, we discuss the implementation of the FCHIP demonstration, which allows eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four States. Budget neutrality estimates for the demonstration will be based on the demonstration period of August 1, 2016 through July 31, 2019. The demonstration includes three intervention prongs, under which specific waivers of Medicare payment rules will allow for enhanced payment: Telehealth, skilled nursing facility/nursing facility services, and ambulance services. These waivers are being implemented with the goal of increasing access to care with no net increase in costs. (We initially addressed this demonstration in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296) and FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517).)

We specified the payment enhancements for the demonstration and selected CAHs for participation with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration program and uncertainty associated with projected Medicare utilization and costs, in the FY 2019 IPPS/LTCH PPS final rule we adopted a contingency plan (83 FR 41516 through 41517) to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. Accordingly, if analysis of claims data for the Medicare beneficiaries receiving services at each of the participating CAHs, as well as of other data sources, including cost reports, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. Thus, in the event that we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, CMS will recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B. Because of the small scale of the demonstration, it would not be feasible to implement budget neutrality by reducing payments only to the participating CAHs. Therefore, we will make the reduction to payments to all CAHs, not just those participating in the demonstration, because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by this provider category. As we explained in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of the Act permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Given the 3-year period of performance of the FCHIP demonstration and the time needed to conduct the budget neutrality analysis, in the event the demonstration is found not to have been budget neutral, we plan to recoup any excess costs over a period of three cost report periods, beginning in CY 2020. Therefore, based on currently available data, this policy will likely have no impact for any national payment system for FY 2020.

I. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the December 2018 update of the FY 2018 MedPAR file and the December 2018 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2018 update of the most recently available hospital cost report data (FYs 2016 and 2017) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment, as described later in this section.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each proposed change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2018 update of the FY 2018 MedPAR file, we simulated payments under the capital IPPS for FY 2019 and the proposed payments for FY 2020 for a comparison of total payments per case. Short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the proposed capital IPPS payments in FY 2020 is as follows:

(Standard Federal rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH adjustment factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- An estimated increase in the Medicare case-mix index of 0.5 percent in FY 2019 and 0.5 percent in FY 2020 based on preliminary FY 2019 data.
- We estimate that Medicare discharges would be approximately 10.8 million in both FYs 2019 and 2020.
- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the Addendum to this proposed rule, the proposed update to the capital Federal rate is 1.5 percent for FY 2020.
- In addition to the proposed FY 2020 update factor, the proposed FY 2020 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 0.9976 and a proposed outlier adjustment factor of 0.9466.

2. Results

We used the actuarial model previously described in section I.I. of Appendix A of this proposed rule to estimate the potential

impact of the proposed changes for FY 2020 on total capital payments per case, using a universe of 3,242 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the December 2018 update of the FY 2018 MedPAR file, the December 2018 update to the PSF, and the most recent cost report data from the December 2018 update of HCRIS. In Table III, we present a comparison of estimated proposed total payments per case for FY 2019 and estimated total payments per case for FY 2020 based on the proposed FY 2020 payment policies. Column 2 shows estimates of payments per case under our model for FY 2019. Column 3 shows estimates of proposed payments per case under our model for FY 2020. Column 4 shows the proposed total percentage change in payments from FY 2019 to FY 2020. The change represented in Column 4 includes the proposed 1.5 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2020 are expected to increase as compared to capital payments per case in FY 2019. This expected increase overall is largely due to the proposed 1.5 percent update to the capital Federal rate for FY 2020. Hospitals within both rural and urban regions may experience an increase or a decrease in capital payments per case due to changes in the GAFs. These regional effects of the proposed changes to the GAFs on capital payments are consistent with the projected changes in payments due to proposed changes in the wage index (and proposed policies affecting the wage index), as shown in Table I in section I.G. of this Appendix A.

The net impact of these proposed changes is an estimated 1.9 percent change in capital payments per case from FY 2019 to FY 2020 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in both urban and rural classifications would experience an increase in capital IPPS payments per case in FY 2020 as compared to FY 2019. Capital IPPS payments per case would increase by an estimated 1.7 percent for hospitals in large urban areas and by 1.8 percent for hospitals in other urban areas, while payments to hospitals in rural areas would increase by 3.1 percent in FY 2019 to FY 2020.

The comparisons by region show that the estimated changes in capital payments per case from FY 2019 to FY 2020 in urban areas range from a 0.4 percent decrease for the New England region to a 3.1 percent increase for the East South Central region. For rural regions, the Pacific rural region is projected to experience an increase in capital IPPS payments per case of 4.1 percent, while the New England rural region is projected to experience an increase in capital IPPS payments per case of 0.6 percent.

Hospitals of all types of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are expected to experience an increase in capital payments per case from FY 2019 to FY 2020. The projected increase in capital payments for voluntary hospitals is estimated to be 1.8 percent. Proprietary hospitals and government hospitals are expected to experience an increase in capital IPPS payments of 2.2 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2020. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this proposed rule for FY 2020, we show the proposed average capital payments per case for reclassified hospitals for FY 2020. Urban reclassified hospitals are expected to experience an increase in capital payments of 1.4 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 2.1 percent. The estimated percentage increase for rural reclassified hospitals is 2.6 percent, and for rural nonreclassified hospitals, the estimated percentage increase in capital payments is 3.9 percent.

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TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2019 PAYMENTS COMPARED TO PROPOSED FY 2020 PAYMENTS]

	Number of Hospitals	Average FY 2019 Payments/ Case	Proposed Average FY 2020 Payments/ Case	Proposed Percent Change
By Geographic Location:				
All hospitals	3,242	$967	$986	1.9
Large urban areas (populations over 1 million)	1,268	$1,041	$1,059	1.7
Other urban areas (populations of 1 million of fewer)	1,208	$965	$1,019	1.8
Urban hospitals	2,476	$1,001	$983	1.9
0-99 beds	643	$811	$829	2.2
100-199 beds	759	$858	$875	1.9
200-299 beds	431	$928	$945	1.8
300-499 beds	424	$1,007	$1,026	1.8
500 or more beds	219	$1,197	$1,218	1.8
Rural hospitals	766	$664	$684	3.1
0-49 beds	302	$558	$586	5.0
50-99 beds	272	$624	$644	3.2
100-149 beds	108	$655	$677	3.3
150-199 beds	45	$715	$734	2.7
200 or more beds	39	$783	$798	1.8
By Region:				
Urban by Region				
New England	112	$1,118	$1,113	-0.4
Middle Atlantic	307	$1,093	$1,107	1.3
South Atlantic	399	$888	$905	1.9
East North Central	386	$958	$974	1.7
East South Central	147	$843	$869	3.1
West North Central	157	$979	$1,005	2.6
West South Central	375	$914	$934	2.2
Mountain	169	$1,033	$1,049	1.6
Pacific	374	$1,270	$1,298	2.2
Rural by Region				
New England	20	$927	$932	0.6
Middle Atlantic	53	$651	$665	2.1
South Atlantic	120	$613	$633	3.1
East North Central	114	$672	$688	2.4
East South Central	150	$609	$633	4.0
West North Central	93	$698	$722	3.4
West South Central	142	$601	$623	3.7
Mountain	50	$761	$784	3.0
Pacific	24	$860	$895	4.1
By Payment Classification:				
All hospitals				
Large urban areas (populations over 1 million)	1,283	$1,040	$986	1.9
Other urban areas (populations of 1 million of fewer)	905	$929	$1,058	1.7

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2019 PAYMENTS COMPARED TO PROPOSED FY 2020 PAYMENTS]

	Number of Hospitals	Average FY 2019 Payments/ Case	Proposed Average FY 2020 Payments/ Case	Proposed Percent Change
Rural areas	1,054	$895	$951	2.4
Teaching Status:				
Non-teaching	2,127	$820	$839	2.3
Fewer than 100 Residents	865	$927	$944	1.8
100 or more Residents	250	$1,342	$1,365	1.7
Urban DSH:				
Non-DSH	538	$906	$924	2.0
100 or more beds	1,393	$1,018	$1,038	2.0
Less than 100 beds	352	$743	$759	2.2
Rural DSH:				
Sole Community (SCH/EACH)	256	$682	$706	3.6
Referral Center (RRC/EACH)	442	$956	$970	1.4
Other Rural:				
100 or more beds	31	$804	$809	0.7
Less than 100 beds	230	$547	$573	4.7
Urban teaching and DSH:				
Both teaching and DSH	776	$1,087	$1,108	1.9
Teaching and no DSH	84	$984	$1,001	1.8
No teaching and DSH	969	$866	$885	2.1
No teaching and no DSH	359	$868	$887	2.1
Rural Hospital Types:				
Plain Rural	171	$692	$711	2.8
SCH/EACH	380	$989	$1,003	1.4
SCH/EACH	305	$755	$780	3.2
SCH, RRC and EACH	143	$795	$811	2.1
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2018 Reclassifications:				
All Urban Reclassified	679	$1,016	$1,031	1.4
All Urban Non-Reclassified	1,753	$992	$1,013	2.1
All Rural Reclassified	278	$688	$706	2.6
All Rural Non-Reclassified	441	$626	$650	3.9
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	$677	$693	2.4
Type of Ownership:				
Voluntary	1,893	$981	$998	1.8
Proprietary	852	$880	$899	2.2
Government	496	$1,009	$1,031	2.2
Medicare Utilization as a Percent of Inpatient Days:				
0-25	596	$1,106	$1,128	2.0
25-50	2,122	$965	$983	1.9
50-65	414	$788	$803	2.0
Over 65	73	$577	$612	6.0

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J. Effects of Proposed Payment Rate Changes and Proposed Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2020. In the preamble of this proposed rule, we specify the statutory authority for the provisions that are presented, identify the proposed policies, and present rationales for our decisions as

well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 384 LTCHs included in this impact analysis. We note that, although there are currently approximately 394 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the proposed FY 2020 MS–LTC–DRG relative weights (discussed in section VII.B.3.c. of the preamble of this proposed rule. Moreover, in the claims data used for this proposed rule, 2 of these 384 LTCHs only have claims for site neutral payment rate cases and, therefore, do not affect our impact analysis for LTCH PPS standard Federal payment rate cases.) In the impact analysis, we used the proposed payment rate, factors, and policies presented in this proposed rule, the proposed 1.027 percent annual update to the LTCH PPS standard Federal payment rate, the one-time budget neutrality adjustment factor for the estimated cost of eliminating the 25-percent threshold policy in FY 2020 as discussed in section VII.D. of the preamble of this proposed rule, the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, and the best available claims and CCR data to estimate the proposed change in payments for FY 2020.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, there are two separate high cost outlier targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. The statute also establishes a transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019. The transitional payment amount for site neutral payment rate cases is a blended payment rate, which is calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge determined under § 412.523. For FY 2019, the applicability of this transitional payment method for site neutral payment rate cases is dependent upon both the discharge date of the case and the start date of the LTCH's FY 2019 cost reporting period. Specifically, the transitional payment method only applies to those site neutral payment rate cases whose discharges occur during a LTCH's cost reporting period that begins before October 1, 2019. While the transitional payment amount for site neutral payment rate cases is a blended payment rate, which is calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge determined under § 412.523, site neutral payment rate cases whose discharges from an LTCH occur during the LTCH's cost reporting period that begins on or after October 1, 2019 are paid the site neutral payment rate amount determined under § 412.522(c)(1).

Based on the best available data for the 384 LTCHs in our database that were considered in the analyses used for this proposed rule, we estimate that overall LTCH PPS payments in FY 2020 will increase by approximately 0.9 percent (or approximately $37 million) based on the proposed rates and factors presented in section VII. of the preamble and section V. of the Addendum to this proposed rule.

The statutory transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2018 or FY 2019 uses a blended payment rate, which is determined as 50 percent of the site neutral payment rate amount for the discharge and 50 percent of the LTCH PPS standard Federal prospective payment rate amount for the discharge (§ 412.522(c)(3)). Therefore, when estimating FY 2019 LTCH PPS payments for site neutral payment rate cases for this impact analysis, the transitional blended payment rate was applied to all such cases because all discharges in FY 2019 are either in the LTCH's cost reporting period that began during FY 2018 or in the LTCH's cost reporting period that will begin during FY 2019. However, when estimating FY 2020 LTCH PPS payments for site neutral payment rate cases for this impact analysis, because the statute specifies that the site neutral payment rate effective date for a given LTCH is based on the date that the LTCH's cost reporting period begins during FY 2020, we included an adjustment to account for this rolling effective date, consistent with the general approach used for the LTCH PPS impact analysis presented in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49831). This approach accounts for the fact that site neutral payment rate cases in FY 2019 that are in an LTCH's cost reporting period that begins before October 1, 2019 continue to be paid under the transitional payment method until the start of the LTCH's first cost reporting period beginning on or after October 1, 2019. Site neutral payment rate cases whose discharges from LTCHs occurring during an LTCH's cost reporting period that begins on or after October 1, 2019 will no longer be paid under the transitional payment method and will instead be paid the site neutral payment rate amount as determined under § 412.522(c)(1).

For purposes of this impact analysis, to estimate proposed total FY 2020 LTCH PPS payments for site neutral payment rate cases, we used the same general approach as was used in the FY 2016 IPPS/LTCH PPS final rule with modifications to account for the rolling end date to the transitional blended payment rate in FY 2020 instead of the rolling effective date for implementation of the transitional site neutral payment rate in FY 2016. In summary, under this approach, we grouped LTCHs based on the quarter their cost reporting periods would begin during FY 2020. For example, LTCHs with cost reporting periods that begin during October through December 2019 would be grouped to site neutral payment rate cases whose discharges would occur during the first quarter of FY 2020. For LTCHs grouped in each quarter of FY 2020, we modeled those LTCHs' estimated FY 2020 site neutral payment rate payments under the transitional blended payment rate based on the quarter in which the LTCHs in each group would continue to be paid the transitional payment method for the site neutral payment rate cases.

For purposes of this estimate, then, we assume the cost reporting period is the same for all LTCHs in each of the quarterly groups and that this cost reporting period begins on the first day of that quarter. (For example, our first group consists of 37 LTCHs whose cost reporting period will begin in the first quarter of FY 2020 so that, for purposes of this estimate, we assume all 37 LTCHs will begin their FY 2020 cost reporting period on October 1, 2019.) Second, we estimated the proportion of FY 2020 site neutral payment rate cases in each of the quarterly groups, and we then assume this proportion is applicable for all four quarters of FY 2020. (For example, as discussed in more detail below, we estimate the first quarter group will discharge 7.1 percent of all FY 2020 site neutral payment rate cases and, therefore, we estimate that group of LTCHs will discharge 7.1 percent of all FY 2018 site neutral payment rate cases in each quarter of FY 2020.) Then, we modeled estimated FY 2020 payments on a quarterly basis under the LTCH PPS standard Federal payment rate based on the assumptions described above. We continue to believe that this approach is a reasonable means of taking the rolling effective date into account when estimating FY 2020 payments.

Based on the fiscal year begin date information in the December 2018 update of the PSF and the LTCH claims from the December 2018 update of the FY 2018 MedPAR files for the 384 LTCHs in our database used for this proposed rule, we found the following: 7.1 percent of site neutral payment rate cases are from 37 LTCHs whose cost reporting periods will begin during the first quarter of FY 2020; 23.4 percent of site neutral payment rate cases are from 94 LTCHs whose cost reporting periods will begin in the second quarter of FY 2020; 9.3 percent of site neutral payment rate cases are from 52 LTCHs whose cost reporting periods will begin in the third quarter of FY 2020; and 60.3 percent of site neutral payment rate cases are from 201 LTCHs whose cost reporting periods will begin in the fourth quarter of FY 2020. Therefore, the following percentages apply in the approach described above:

- First Quarter FY 2020: 7.1 percent of site neutral payment rate cases (that is, the percentage of discharges from LTCHs whose FY 2018 cost reporting period will begin in the first quarter of FY 2020) are no longer eligible for the transitional blended payment method, while the remaining 92.9 percent of site neutral payment rate discharges are eligible to be paid under the transitional payment method.
- Second Quarter FY 2020: 30.4 percent of site neutral payment rate second quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting period will begin in the first or second quarter of FY 2020) are no longer eligible for the transitional blended payment method, while the remaining 69.6 percent of site neutral payment rate second quarter discharges are eligible to be paid under the transitional payment method.
- Third Quarter FY 2020: 39.7 percent of site neutral payment rate third quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting period will begin in the first, second, or third quarter of FY 2020) are no longer eligible for the transitional blended payment method while the remaining 60.3 percent of site neutral payment rate third quarter discharges are eligible to be paid under the transitional payment method.
- Fourth Quarter FY 2020: 100.0 percent of site neutral payment rate fourth quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting period will begin in the first, second, third, or fourth quarter of FY 2020) are no longer eligible for the transitional blended payment method.

Based on the FY 2018 LTCH cases that were used for the analysis in this proposed rule, approximately 29 percent of those cases were classified as site neutral payment rate cases (that is, 29 percent of LTCH cases did not meet the patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2020 will not change significantly from the most recent historical data. Taking into account the transitional blended payment rate and other changes that will apply to the site neutral payment rate cases in FY 2020, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will decrease by approximately 4.9 percent (or approximately $41 million).

Approximately 71 percent of LTCH cases are expected to meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2020, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2020 will increase approximately 2.3 percent (or approximately $79 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2020 is primarily due to the proposed 2.7 percent annual update to the LTCH PPS standard Federal payment rate for FY 2020 and the estimated 0.3 percent decrease in high cost outlier payments discussed in section V.D.3.b.(3). of the Addendum to this proposed rule.

Based on the 384 LTCHs that were represented in the FY 2018 LTCH cases that were used for the analyses in this proposed rule presented in this Appendix, we estimate that aggregate FY 2019 LTCH PPS payments will be approximately $4.274 billion, as compared to estimated aggregate FY 2020 LTCH PPS payments of approximately $4.311 billion, resulting in an estimated overall increase in LTCH PPS payments of approximately $37 million. We note that the estimated $37 million increase in LTCH PPS payments in FY 2020 does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the proposed policies in this proposed rule.

The LTCH PPS standard Federal payment rate for FY 2019 is $41,558.68. For FY 2020, we are proposing to establish an LTCH PPS standard Federal payment rate of $42,950.91 which reflects the proposed 2.7 percent annual update to the LTCH PPS standard Federal payment rate, the proposed one-time budget neutrality adjustment factor of 0.999856 for eliminating the 25-percent threshold policy in FY 2020 as discussed in section VII.D. of the preamble of this proposed rule, and the proposed area wage budget neutrality factor of 1.0064747 to ensure that the changes in the wage indexes and labor-related share do not influence aggregate payments. For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of $42,114.47. This proposed LTCH PPS standard Federal payment rate reflects the proposed updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP. We note that the factors previously described to determine the proposed FY 2020 LTCH PPS standard Federal payment rate are applied to the FY 2019 LTCH PPS standard Federal rate set forth under § 412.523(c)(3)(xiv) (that is, $41,558.68).

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the proposed annual update of 2.7 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 2.6 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2019 to FY 2020, on average, for all LTCHs (Column 6). In addition to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2020, the estimated increase of 2.6 percent shown in Column 6 of Table IV also includes estimated payments for SSO cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. Therefore, for all hospital categories, the projected increase in payments based on the proposed LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases is somewhat less than the proposed 2.7 percent annual update for FY 2020.

For FY 2020, we are proposing to update the wage index values based on the most recent available data, and we are proposing to continue to use labor market areas based on the CBSA delineations (as discussed in section V.B. of the Addendum to this proposed rule). In addition, we are proposing the labor-related share would remain at 66.0 percent under the LTCH PPS for FY 2020, based on the most recent available data on the relative importance of the labor-related share of operating and capital costs of the 2013-based LTCH market basket. We also are proposing to apply a proposed area wage level budget neutrality factor of 1.0064747 to ensure that the changes to the wage data and labor-related share do not result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

We currently estimate total high cost outlier payments for LTCH PPS standard Federal payment rate cases would decrease from FY 2019 to FY 2020. Based on the FY 2018 LTCH cases that were used for the analyses in this proposed rule, we estimate that the FY 2019 high cost outlier threshold of $27,121 (as established in the FY 2019 IPPS/LTCH PPS final rule correction notice) would result in estimated high cost outlier payments for LTCH PPS standard Federal payment rate cases in FY 2019 that are projected to exceed the 7.975 percent target. Specifically, we currently estimate that high cost outlier payments for LTCH PPS standard Federal payment rate cases would be approximately 8.24 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2019. Combined with our estimate that FY 2020 high cost outlier payments for LTCH PPS standard Federal payment rate cases would be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2020, this would result in an estimated decrease in high cost outlier payments of approximately 0.3 percent between FY 2019 and FY 2020. We note that, consistent with past practice, in calculating these estimated high cost outlier payments, we increased estimated costs by an inflation factor of 6.0 percent (determined by the Office of the Actuary) to update the FY 2018 costs of each case to FY 2020.

Table IV shows the estimated impact of the proposed payment rate and proposed policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2020 by comparing estimated FY 2019 LTCH PPS payments to estimated FY 2020 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.4. of this Appendix.

As we discuss in detail throughout this proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS, which are projected to result in an overall increase in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS

payment amounts would result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 2.2 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This estimated impact is based on the FY 2018 data for the 19 rural LTCHs (out of 384 LTCHs) that were used for the impact analyses shown in Table IV.

3. Effect of Proposed Payment Adjustment for LTCH Discharges That Do Not Meet the Applicable Discharge Payment Percentage

In section VII.C. of the preamble of this proposed rule, we discuss our proposal to implement the requirements of section 1886(m)(6)(C)(ii) of the Act, which specifies for cost reporting periods beginning on or after October 1, 2019, any LTCH with a discharge payment percentage for the period that is not at least 50 percent will be informed of such a fact, and all of the LTCH's discharges in each successive cost reporting period will be paid the payment amount that would apply under subsection (d) for the discharge if the hospital were a subsection (d) hospital, subject to the process for reinstatement provided for by section 1886(m)(6)(C)(iii) of the Act. Specifically, we are proposing to continue to use our existing policy to calculate the discharge payment percentage and to inform LTCHs when their discharge payment percentage for the period is not at least 50 percent. We also are proposing that an LTCH would become subject to this payment adjustment for each cost reporting period after its calculated discharge payment percentage that is not at least 50 percent.

To establish a reinstatement process as required by the statute, we are proposing that the payment adjustment for an LTCH would be discontinued beginning with the discharges occurring in the cost reporting period after the LTCH's discharge payment percentage is calculated to be at least 50 percent. Furthermore, we are proposing a probationary-cure period that would allow an LTCH the opportunity to have the payment adjustment suspended for a cost reporting period if, for the period of at least 5 consecutive months of the immediately preceding 6-month period, the discharge payment percentage is at least 50 percent. Under the proposed probationary-cure period, an LTCH would have an opportunity to delay the application of the payment adjustment until the end of the cost reporting period, and waive the payment adjustment for that cost reporting period if the discharge payment percentage for that cost reporting period is ultimately found to be at least 50 percent.

As noted above, under our proposal, an LTCH would be first subject to a potential payment adjustment based on the hospital's discharge payment percentage for its FY 2020 cost reporting period. Hospitals would be notified of that percentage in FY 2021, with the payment adjustment taking effect in FY 2022. Therefore, we do not estimate any effect on LTCH PPS payments until FY 2022. Based on the most recent information available at the time of development of this proposed rule, we estimate that, for FY 2022, our proposal would reduce Medicare spending under the LTCH PPS by approximately $60 million. While we expect that there would be less than the maximum estimated savings due to the proposed inclusion of a provisional-cure period, at this time we do not have a reliable estimate of the effect of that policy on the estimated savings.

Based on the FY 2017 claims data (the most recent set of full claims available), on average, each discharge from an LTCH that fails to meet the 50-percent patient discharge threshold would result in a payment decrease of approximately $20,200 for LTCH PPS standard Federal payment rate discharges and an estimated payment increase of approximately $1,700 for site neutral payment rate discharges. To estimate the number of discharges, we assumed that LTCHs that fail to meet the 50-percent patient discharge threshold are those whose discharge payment percentage is below 40 percent based on FY 2017 claims data. We expect that an LTCH whose discharge payment percentage is at least 40 percent based on FY 2017 claims data will adjust its admission/discharge practices, such that it would no longer be below the 50-percent patient discharge threshold. Applying our actuary's assumption of a 74-percent to 26-percent split between LTCH PPS standard Federal payment rate discharges and site neutral payment rate discharges in FY 2022, we estimate there would be 3,475 LTCH PPS standard Federal payment rate discharges and 8,670 site neutral payment rate discharges. The FY 2017 estimate is inflated to FY 2022, resulting in estimated savings of $60 million (comprised of approximately $80 million in savings from LTCH PPS standard Federal payment rate discharges and approximately $20 million in costs from site neutral payment rate discharges).

4. Anticipated Effects of Proposed LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, reduced by 4.6 percent for FYs 2018 through 2026, including any applicable HCO payments, or 100 percent of the estimated cost of the case, reduced by 4.6 percent. The statute also establishes a transitional payment method for cases that are paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019, under which the site neutral payment rate cases are paid based on a blended payment rate calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge.

As discussed in section I.J. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2020 of approximately $37 million. This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $79 million and the projected decrease in payments to site neutral payment rate cases of approximately $41 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section V.D. of the Addendum to this proposed rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this proposed rule to project estimated FY 2020 LTCH PPS payments (that is, FY 2018 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the proposed change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the proposed changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects proposed changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.4. of this Appendix refers only to the impact on proposed LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the proposed changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is

currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), reduced by 4.6 percent for FYs 2018 through 2026, including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the proposed changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this proposed rule on different categories of LTCHs for FY 2020, it is necessary to estimate payments per discharge for FY 2019 using the rates, factors, and the policies established in the FY 2019 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2020 using the proposed rates, factors, and the policies in this FY 2020 IPPS/LTCH PPS proposed rule (as discussed in section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). As discussed elsewhere in this proposed rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: Large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Calculation of Proposed LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our proposed policies on proposed payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2019 and proposed FY 2020 payments on a case-by-case basis using historical LTCH claims from the FY 2018 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2018 MedPAR files. For modeling FY 2019 LTCH PPS payments, we used the FY 2019 standard Federal payment rate of $41,558.68 (or $40,738.57 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). Similarly, for modeling payments based on the proposed FY 2020 LTCH PPS standard Federal payment rate, we used the proposed FY 2020 standard Federal payment rate of $42,950.91 (or $42,114.47 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2019 LTCH PPS payments, we used the current FY 2019 labor-related share (66.0 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2019 IPPS/LTCH PPS final rule (which are available via the internet on the CMS website), the FY 2019 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,121 (as reflected in the FY 2019 IPPS/LTCH PPS correction notice to the final rule), and the FY 2019 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2019 nonlabor-related share (34.0 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling proposed FY 2020 LTCH PPS payments, we used the proposed FY 2020 LTCH PPS labor-related share (66.0 percent), the proposed FY 2020 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are available via the internet on the CMS website), the proposed FY 2020 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $29,997 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2020 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the FY 2020 nonlabor-related share (34.0 percent) for LTCHs located in Alaska and Hawaii. We note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 2.7 percent (determined by the Office of the Actuary) to update the FY 2018 costs of each case to FY 2019, and an inflation factor of 6.0 percent (determined by the Office of the Actuary) to update the FY 2018 costs of each case to FY 2020.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2019 to FY 2020 based on the proposed payment rates and proposed policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the proposed change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2019 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated FY 2020 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2019 to FY 2020 due to the proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2019 to FY 2020 for proposed changes to the area wage level adjustment (that is, the wage indexes and the labor-related share), including the application of the proposed area wage level budget neutrality factor (as discussed in section V.B. of the Addendum to this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2019 (Column 4) to FY 2020 (Column 5) for all proposed changes.

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TABLE IV: IMPACT OF PROPOSED PAYMENT RATE AND PROPOSED POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2020 (ESTIMATED FY 2019 PAYMENTS COMPARED TO ESTIMATED PROPOSED FY 2020 PAYMENTS)

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2019 LTCH PPS Payment Per Standard Payment Rate (4)	Average Proposed FY 2020 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Proposed Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Proposed Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Proposed Standard Payment Rate Changes[4] (8)
ALL PROVIDERS	384	72,375	$47,472	$48,561	2.6	0.0	2.3
BY LOCATION:							
RURAL	19	2,597	$38,012	$38,835	2.6	0.4	2.2
URBAN	365	69,778	$47,824	$48,923	2.6	0.0	2.3
LARGE	180	37,654	$51,477	$52,614	2.6	-0.1	2.2
OTHER	185	32,124	$43,543	$44,597	2.6	0.1	2.4
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	44	9,280	$53,667	$54,747	2.6	-0.1	2.0
OCT. 1983 - SEPT. 1993	13	2,603	$45,098	$46,275	2.6	0.1	2.6
OCT. 1993 - SEPT. 2002	176	33,689	$45,974	$47,081	2.6	0.1	2.4
AFTER OCTOBER 2002	151	26,803	$47,441	$48,503	2.6	-0.1	2.2

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2019 LTCH PPS Payment Per Standard Payment Rate (4)	Average Proposed FY 2020 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Proposed Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Proposed Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Proposed Standard Payment Rate Changes[4] (8)
BY OWNERSHIP TYPE:							
VOLUNTARY	75	10,389	$48,981	$50,195	2.6	0.0	2.5
PROPRIETARY	295	60,235	$47,038	$48,099	2.6	0.0	2.3
GOVERNMENT	14	1,751	$53,457	$54,769	2.6	0.2	2.5
BY REGION:							
NEW ENGLAND	10	2,464	$44,497	$45,491	2.6	-0.2	2.2
MIDDLE ATLANTIC	25	5,838	$53,511	$54,692	2.6	-0.2	2.2
SOUTH ATLANTIC	63	11,172	$46,241	$47,404	2.6	0.0	2.5
EAST NORTH CENTRAL	25	4,317	$45,234	$46,315	2.6	0.2	2.4
EAST SOUTH CENTRAL	64	13,723	$47,533	$48,560	2.6	-0.1	2.2
WEST NORTH CENTRAL	32	5,929	$42,496	$43,465	2.6	0.0	2.3
WEST SOUTH CENTRAL	111	18,098	$42,138	$43,098	2.6	0.1	2.3
MOUNTAIN	30	3,711	$48,643	$49,728	2.6	0.1	2.2
PACIFIC	24	7,123	$63,806	$65,297	2.6	-0.1	2.3
BY BED SIZE:							
BEDS: 0-24	40	4,471	$45,935	$47,272	2.6	0.5	2.9

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2019 LTCH PPS Payment Per Standard Payment Rate (4)	Average Proposed FY 2020 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Proposed Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Proposed Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Proposed Standard Payment Rate Changes[4] (8)
BEDS: 25-49	174	25,525	$44,098	$45,049	2.6	0.0	2.2
BEDS: 50-74	93	17,861	$49,193	$50,258	2.6	-0.2	2.2
BEDS: 75-124	44	12,261	$51,271	$52,537	2.6	0.0	2.5
BEDS: 125-199	24	7,759	$47,914	$49,010	2.6	0.1	2.3
BEDS: 200+	9	4,498	$50,197	$51,431	2.6	0.0	2.5

[1] Estimated FY 2020 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the proposed payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2019 to FY 2020 for the proposed annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2019 to FY 2020 for proposed changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this proposed rule).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2019 (shown in Column 4) to FY 2020 (shown in Column 5), including all of the proposed changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this proposed rule. We note that this column, which shows the proposed percent change in estimated payments per discharge for all proposed changes, does not equal the sum of the proposed percent changes in estimated payments per discharge for the proposed annual update to the LTCH PPS standard Federal payment rate (Column 6) and the proposed changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in estimated payments to aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

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d. Results

Based on the FY 2018 LTCH cases (from 384 LTCHs) that were used for the analyses in this proposed rule, we have prepared the following summary of the impact (as shown in Table IV) of the proposed LTCH PPS payment rate and proposed policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are projected to increase 2.3 percent, on average, for all LTCHs from FY 2019 to FY 2020 as a result of the proposed payment rate and proposed policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 2.3 percent increase in LTCH PPS

payments per discharge was determined by comparing estimated FY 2020 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2019 LTCH PPS payments for LTCH discharges which would be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.4. of this Appendix).

As stated previously, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2020 by 2.7 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. In addition, we are proposing to apply the one-time budget neutrality adjustment factor of 0.999856 for the cost of eliminating the 25-percent threshold policy in FY 2020 as discussed in section VII.D. of the preamble of this proposed rule. Consistent with § 412.523(d)(4), we also are proposing to apply an area wage level budget neutrality factor to the proposed FY 2020 LTCH PPS standard Federal payment rate of 1.0064747, based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. As we also explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the proposed 2.7 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 2.6 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2019 to FY 2020. This is because our estimate of the proposed changes in payments due to the proposed update to the LTCH PPS standard Federal payment rate also reflects estimated payments for SSO cases that are paid using a methodology that is not entirely affected by the update to the LTCH PPS standard Federal payment rate. Consequently, for certain hospital categories, we estimate that payments to LTCH PPS standard Federal payment rate cases may increase by less than 2.7 percent due to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2020.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the proposed overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2019 to FY 2020 for all hospitals is 2.3 percent. For rural LTCHs, estimated payments for LTCH PPS standard Federal payment rate cases are expected to increase 2.2 percent. For urban LTCHs, we estimate an increase of 2.3 percent from FY 2019 to FY 2020. Among the urban LTCHs, large urban LTCHs are projected to experience an increase of 2.2 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2019 to FY 2020, and such payments for the remaining urban LTCHs are projected to increase 2.4 percent, as shown in Table IV.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the most recent available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 47 percent) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002, and they are projected to experience a 2.4 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2019 to FY 2020, as shown in Table IV.

Approximately 11 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an average percent increase of 2.0 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2019 to FY 2020. Approximately 3 percent of LTCHs began participating in the Medicare program between October 1983 and September 1993, and these LTCHs are projected to experience an increase of 2.6 percent in estimated payments for LTCH PPS standard Federal payment rate cases from FY 2019 to FY 2020. LTCHs that began participating in the Medicare program after October 1, 2002, which treat approximately 37 percent of all LTCH PPS standard Federal payment rate cases, are projected to experience a 2.2 percent increase in estimated payments from FY 2019 to FY 2020.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: voluntary, proprietary, and government. Based on the most recent available data, approximately 20 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 77 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 4 percent of LTCHs. Based on ownership type, voluntary LTCHs are expected to experience a 2.5 percent increase in payments to LTCH PPS standard Federal payment rate cases, while proprietary LTCHs are expected to experience an average increase of 2.3 percent in payments to LTCH PPS standard Federal payment rate cases. Government owned and operated LTCHs, meanwhile, are expected to experience a 2.5 percent increase in payments to LTCH PPS standard Federal payment rate cases from FY 2019 to FY 2020.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2020 are projected to increase across all census regions. LTCHs located in the South Atlantic are projected to experience the largest increase at 2.5 percent followed by the East North Central at 2.4 percent. The remaining regions are projected to increase by either 2.2 or 2.3 percent. These regional variations are largely due to proposed updates in the wage index.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. We project that LTCHs with 0–24 beds will experience the largest increase in payments for LTCH PPS standard Federal payment rate cases of 2.9 percent. LTCHs with 25–49 beds and 50–74 beds are both projected to experience an increase of 2.2 percent. LTCHs with 75–124 beds and LTCHs with 200+ beds are both projected to experience an increase of 2.5 percent. LTCHs with 125–199 beds are projected to experience an increase in payments of 2.3 percent.

5. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule would result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2020 relative to FY 2019 of approximately $79 million (or approximately 2.3 percent) for the 384 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this proposed rule would result in a decrease in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2020 relative to FY 2019 of approximately $41 million (or approximately −4.9 percent) for the 384 LTCHs in our database. Therefore, we project that the provisions of this proposed rule would result in an increase in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2020 relative to FY 2019 of approximately $37 million (or approximately 0.9 percent) for the 384 LTCHs in our database.

6. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this proposed rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed above, we do not expect the continued implementation of the site neutral payment system to have a negative impact on access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Proposed Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section VIII.A. of the preamble of this proposed rule, we discuss our current and proposed requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2021 payment determination and subsequent years.

In this proposed rule, we are proposing to: (1) Adopt two new opioid-related eCQMs, Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) and Hospital Harm—Opioid-Related Adverse Events eCQM, beginning with the CY 2021 reporting period/FY 2023 payment determination; (2) adopt the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (Hybrid HWR measure) (NQF #2879) in a stepwise manner, beginning with two years of voluntary reporting periods which would run from July 1, 2021 through June 30, 2022, and from July 1, 2022 through June 30, 2023, before requiring reporting of the measure for the reporting period that would run from July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination and subsequent years; (3) remove the Claims-Based Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789) (HWR claims-only measure) beginning with the FY 2026 payment determination; (4) extend the current eCQM reporting and submission requirements for the CY 2020 reporting period/FY 2022 payment determination and CY 2021 reporting period/FY 2023 payment determination; (5) change the eCQM reporting and submission requirements for the CY 2022 reporting period/FY 2024 payment determination, such that hospitals would be required to report one, self-selected calendar quarter of data for: (a) Three self-selected eCQMs, and (b) the proposed Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e), for a total of four eCQMs; (6) continue requiring that EHRs be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years; and (7) establish reporting and submission requirements for the Hybrid HWR measure.

We estimate a total information collection burden increase of 2,211 hours (associated with our proposal to adopt the Hybrid HWR measure) and a total cost increase related to information collection of approximately $83,266 (due to this proposal and our updated hourly wage plus benefits estimate), beginning with the first voluntary reporting period, which runs from July 1, 2021 through June 30, 2022. We refer readers to section X.B.3. of the preamble of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the burden for submitting data to the Hospital IQR Program.

With regard to our proposals to add two new opioid-related eCQMs to the eCQM measure set, while we expect no change to the information collection burden for the Hospital IQR Program as discussed in section X.B.3.b. of the preamble of this proposed rule because we are also propos eCQM reporting requirements such that the total number of eCQMs that would be reported and the total quarters of data would remain unchanged from previously finalized requirements, we expect some investment in EHR system updates. We are also proposing that hospitals use certified electronic heath record technology (CEHRT) that are certified to report all available eCQMs. We expect no change to the information collection burden for the Hospital IQR Program as discussed in section X.B.3.e.(3) of the preamble of this proposed rule because this policy does not require hospitals to submit new data to CMS and we do not require CEHRT to be recertified each time it is updated to a more recent version of the eCQM electronic specifications. However, for certifying new eCQMs in the eCQM measure set, we expect some costs for hospitals and EHR vendors in certifying the two new proposed eCQMs so that hospitals have the option to report the new eCQMs if they are finalized. For all of these proposals, due to the differences in the build of respective CEHRT deployed in hospitals, the mapping required to capture required data for measure calculation, and the range of hospital participation in the development, implementation, and testing of new CEHRT functionality, an estimated cost impact of the proposals is not quantifiable as it will vary by CEHRT and hospital.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements of this Program. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years.

L. Effects of Proposed Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section VIII.B. of the preamble of this proposed rule, we discuss our proposed policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In section VIII.B.3.b. of the preamble of this proposed rule, we are proposing to remove one web-based, structural measure beginning with the FY 2022 program year: External Beam Radiotherapy (EBRT) for Bone Metastases (formerly NQF #1822). In addition, in section VIII.B.4. of the preamble of this proposed rule, we are proposing to adopt a claims-based measure for the FY 2022 program year and subsequent years: Surgical Treatment Complications for Localized Prostate Cancer.

As explained in section X.B.4. of the preamble of this proposed rule, we anticipate that the proposed removal of the External Beam Radiotherapy (EBRT) for Bone Metastases (formerly NQF #1822) measure will reduce the overall burden on participating PCHs by 15-mins per PCH. We estimate a total annual reduction of approximately 3 hours for all 11 PCHs (15 minutes $\times$ 11 PCHs/60 minutes per hour), due to the proposed removal of this measure.

We do not anticipate any change in burden on the PCHs associated with our proposed adoption of the Surgical Treatment Complications for Localized Prostate Cancer measure into the PCHQR Program beginning with the FY 2022 program year. This measure is claims-based and does not require PCHs to report any additional data beyond that already submitted on Medicare administrative claims for payment purposes. Therefore, we do not believe that there would be any associated change in burden resulting from this proposal.

M. Effects of Proposed Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

Under the LTCH QRP, the Secretary must reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not complied with the LTCH QRP requirements specified for that fiscal year. Information is not available to determine the precise number of LTCHs that will not meet the requirements to receive the full annual update for the FY 2020 payment determination.

We believe that the burden and costs associated with the LTCH QRP is the time and effort associated with complying with the requirements of the LTCH QRP. We intend to closely monitor the effects of this quality reporting program on LTCHs to help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and help desk support.

We refer readers to section X.B.6. of the preamble of this proposed rule (information collection requirements) for a detailed discussion of the burden associated with the proposed new requirements for the LTCH QRP.

N. Effects of Proposed Requirements Regarding the Promoting Interoperability Program

In section VIII.D. of the preamble of this proposed rule, we discuss our current and proposed requirements for eligible hospitals and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs.

In this proposed rule, we are proposing the following changes to the Medicare Promoting Interoperability Program: (1) Eliminate the requirement that, for the FY 2020 payment adjustment year, for an eligible hospital that has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period in CY 2019 must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2019; (2) establish an EHR reporting period of a minimum of any continuous 90-day period in CY 2021 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program attesting to CMS; (3) require that the Medicare Promoting Interoperability Program measure actions must occur within the EHR reporting period

beginning with the EHR reporting period in CY 2020; (4) revise the Query of PDMP measure to change the reporting requirement from numerator and denominator to a ''yes/no'' response beginning with CY 2019 for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program, make it an optional measure worth five bonus points in CY 2020, remove the exclusions associated with this measure in CY 2020, and clearly state our intended policy that the measure is worth a full 5 bonus points in CY 2019 and CY 2020; (5) change the maximum points available for the e-Prescribing measure to 10 points beginning in CY 2020, in the event we finalize the proposed changes to the Query of PDMP measure; (6) remove the Verify Opioid Treatment Agreement measure beginning in CY 2020 and clearly state our intended policy that the measure is worth a full 5 bonus points in CY 2019; and (7) revise the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to more clearly capture the previously established policy regarding CHERT use. We are also proposing to amend our regulations to incorporate several of these proposals.

For CQM reporting under the Medicare and Medicaid Promoting Interoperability Programs, in section VIII.D.6. of the preamble of this proposed rule, we are making a number of proposals with respect to the reporting of CQM data, including proposing to add two opioid-related measures beginning with the reporting period in CY 2021 and proposing the reporting period, reporting criteria, submission period, and form and method requirements for CQM reporting in CY 2020. However, for the reporting period in CY 2020, these proposals are continuations of current policies and therefore we do not believe that there would be a change in burden for CY 2020.

As explained in section X.B.9. of the preamble of this proposed rule, we estimate for CY 2020 a total information collection burden decrease of 2,200 hours, associated with our proposal to revise the Query of PDMP measure to change the reporting requirement from numerator and denominator to a ''yes/no'' response beginning with CY 2019 for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program, and a total cost decrease of $130,102.50 related to information collection burden cost estimates due to this proposal and our updated hourly wage plus benefits estimate.

O. Alternatives Considered

This proposed rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Wage Index

We considered a number of alternatives to our proposed policies discussed in section III.N.3. of the preamble of this proposed rule to address wage index disparities. As described more fully in section III.N.3.b. of the preamble of this proposed rule, we are proposing to maintain budget neutrality for our proposal to increase the wage index for hospitals with wage index values below the 25th percentile wage index value (that is, low wage index hospitals) by reducing the wage index of hospitals with wage index values above the 75th percentile wage index value (that is, high wage index hospitals). Specifically, as described in section III.N.3.b. of this proposed rule, we are proposing to implement budget neutrality by reducing the distance between the otherwise applicable wage index for high wage index hospitals and the 75th percentile wage index across all hospitals. As an alternative to this proposed budget neutrality approach, we considered applying a budget neutrality factor to the standardized amount rather than focusing the adjustment on the wage index of high wage index hospitals. This alternative approach would have been similar to the budget neutrality approach proposed for the transition, as described more fully in section III.N.3.d. of the preamble of this proposed rule.

As another alternative to addressing wage index disparities, we also considered mirroring our proposed approach of raising the wage index for low wage index hospitals in reducing the wage index values for high wage index hospitals. As described more fully in section III.N.3.a. of the preamble of this proposed rule, we are proposing to increase the wage index for hospitals with a wage index below the 25th percentile wage index. The proposed increase in the wage index for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for these hospitals and the 25th percentile wage index value. Under the alternative considered, we also would decrease the wage index for hospitals with a wage index above the 75th percentile wage index by half the difference between the otherwise applicable final wage index value for these hospitals and the 75th percentile wage index value. We would make the estimated net effect on payments of (1) the increase in the wage index for hospitals below the 25th percentile and (2) the decrease in the wage index for hospitals above the 75th percentile budget neutral through an adjustment to the standardized amount.

A third alternative we considered to address wage index disparities was the creation of a national rural wage index area. We considered whether there currently exists a national rural labor market for hospital labor and, if not, whether we should facilitate the creation of such a national rural labor market through the establishment of this national rural wage index area. Currently, we use statewide rural wage index areas based on the non-MSA area of each State. Under the alternative we considered, we would create a single national rural wage index area. A single national rural wage index area and rural wage index value would arguably partially address wage index disparities because the current rural area in each State with a wage index value below the national rural wage index value would rise to the national rural wage index value. A national rural labor market area would also act to mitigate the incentives to manipulate the rural floor because the effect of such manipulations on the rural average hourly wage would be spread across the national rural wage index area rather than targeted in a single State. However, it should also be noted that the establishment of a national rural wage index area would have a negative impact on hospitals in the rural areas in States with current rural wage index values above the national rural wage index value because these current wage index values would decline to the national rural wage index value.

In order to facilitate public consideration of these alternatives considered for addressing wage index disparities, we have created a file at the hospital level of the different wage index values for each hospital under each of these alternatives considered. This file is available on the FY 2020 proposed rule web page on the CMS website as part of the FY 2020 Proposed Rule Data Files.

2. New Technology Add-On Payments

As discussed in section II.H.8. of the preamble of this proposed rule, in situations where a new medical device is part of the Breakthrough Devices Program and has received FDA marketing authorization, we are proposing an alternative inpatient new technology add-on payment pathway to facilitate access to this technology for Medicare beneficiaries. We also considered whether it would be appropriate to apply this alternative inpatient new technology add-on payment pathway in situations where a new drug is part of an FDA expedited program for drugs and has received FDA marketing authorization. However, in reviewing this issue, we noted that the current drug-pricing system provides generous incentives for innovation, but too often fails to deliver important medications at an affordable cost. Making this policy applicable to drugs would further incentive innovation but without decreasing cost, a key priority of this Administration. In May 2018, President Donald Trump and HHS Secretary Alex Azar released the American Patients First blueprint, a comprehensive plan to lower drug prices and out-of-pocket costs. Since the launch of the blueprint, we have been taking action to turn the President's vision into action, and improve the health and well-being of every American. While we continue to work on these initiatives for drug affordability, we believe that it is appropriate to distinguish between drugs and devices in our consideration of a proposed policy change for transformative new technologies.

3. Uncompensated Care Payments

Another policy area where an alternative was considered was in the calculation of the FY 2020 Medicare uncompensated care payments to hospitals, as discussed in greater detail in section IV.F.4.c. of the preamble of this proposed rule. We are proposing to use Worksheet S–10 data from the FY 2015 cost reports in the calculation of Factor 3 for FY 2020. Although we are proposing to use Worksheet S–10 data from the FY 2015 cost reports, we acknowledge that some hospitals have raised concerns regarding the cost reporting instructions in effect for FY 2015, especially compared to the reporting

instructions that were effective for cost reporting periods beginning on or after October 1, 2016. Therefore, as discussed in section IV.F.4.c. of the preamble of this proposed rule, we also are seeking public comments on whether, due to the changes in the cost reporting instructions, we should use a single year of uncompensated care data from the FY 2017 reports, instead of the FY 2015 reports, to calculate Factor 3 for FY 2020.

4. LTCHs

Another policy area where an alternative was considered was in the reinstatement process for LTCHs that do not meet the applicable discharge payment percentage, as discussed in greater detail in section VII.C. of the preamble of this proposed rule. We are proposing to implement a special probationary reinstatement process. Although we are proposing to use a special probationary reinstatement process, we believe the normal reinstatement process discussed in more detail in section VII.C. of the preamble of this proposed rule would satisfy the statutory requirement without further modification. Additionally, as discussed in more detail in section VII.C. of the preamble of this proposed rule, in developing our proposals for the a special probationary reinstatement process, we are concerned that hospitals may be able to manipulate discharges or delay billing in such a way as to artificially inflate their discharge payment percentage for purposes of a special reinstatement process if the special reinstatement process were not probationary. We are soliciting public comments on whether to have a special reinstatement process and, if so, whether it should be probationary.

5. eCQM

As discussed in section VIII.A.9.d.(4) of the preamble of this proposed rule, in the context of proposing eCQM reporting and submission requirements under the Hospital IQR Program for the CY 2022 reporting period/FY 2024 payment determination, hospitals would be required to report one, self-selected calendar quarter of data for three self-selected eCQMs and for all hospitals to report the proposed Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) as their fourth eCQM. We also considered an alternative whereby hospitals would have the option to select one of the two proposed opioids-related eCQMs, the Safe Use of Opioids eCQM or Opioid-Related Adverse Events eCQM, as their fourth required eCQM. However, such an approach would add additional complexity to the eCQM reporting requirements, and we believe that the Safe Use of Opioids eCQM is more closely related to combating the current opioid epidemic, as discussed in sections VIII.A.5.a. and VIII.A.9.d.(4) of the preamble of this proposed rule, than the Opioid-Related Adverse Events eCQM, which is focused on improved monitoring of patients who receive opioids during hospitalization. Because the alternative considered would not impact the collection of information for hospitals, we do not expect these alternatives to affect the reporting burden on hospitals. We considered this alternative and are seeking public comment on it.

P. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This proposed rule, if finalized, is considered an E.O. 13771 regulatory action. We estimate that this rule generates approximately $2.4 million in annualized costs, discounted at 7 percent relative to fiscal year 2016, over a perpetual time horizon.

We discuss the estimated burden and costs for the Hospital IQR Program in section X.B.3. of the preamble of this proposed rule, and estimate that the impact of these proposed changes is an increase in costs of approximately $25 per hospital annually or approximately $83,266 for all hospitals annually.

We discuss the estimated burden and cost reductions for the PCHQR Program in section X.B.4. of the preamble of this proposed rule, and estimate that the impact of these proposed changes is a reduction in costs of approximately $10 per PCH annually or approximately $113 for all participating PCHs annually.

We discuss the estimated burden for the LTCH QRP in section X.B.6. of the preamble of this proposed rule, and estimate that the impact of these proposed changes is an increase in costs of approximately $5,499.63 per LTCH annually or approximately $2,282,346 for all LTCHs annually.

We do not anticipate an increase or decrease in burden and costs for the Hospital Readmissions Reduction Program, the HAC Reduction Program, or the Hospital Value-Based Purchasing Program based on the proposed policies in this proposed rule.

Also, as noted in section I.R. of this Appendix, the regulatory review cost for this proposed rule is $1,905,475.

Section of the proposed rule	Description	Amount of costs or savings
Section X.B.3. of the preamble	ICRs for the Hospital IQR Program	$83,266
Section X.B.4. of the preamble	ICRs for the PCHQR Program	($113)
Section X.B.6. of the preamble	ICRs for the LTCH QRP	2,282,346
Total		2,365,499

Q. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $4.67 billion in FY 2020, taking into account operating, capital, new technology, and low volume hospital payments as modeled for this proposed rule. Approximately $4.4 billion of this estimated increase is due to the proposed changes in operating payments, including $0.2 billion in uncompensated care payments (discussed in sections I.G. and I.H. of this Appendix), approximately $174 million is due to the change in capital payments (discussed in section I.I. of this Appendix), approximately $110 million is due to the change in new technology add-on payments (discussed in section I.H. of this Appendix), and approximately $25 million is due to the change in low-volume hospital payments (discussed in section I.H. of this Appendix). Total differs from the sum of the components due to rounding.

Table I. of section I.G. of this Appendix also demonstrates the estimated redistributional impacts of the IPPS budget neutrality requirements for the proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB.

We estimate that hospitals would experience a 1.9 percent increase in capital payments per case, as shown in Table III. of section I.I. of this Appendix. We project that there would be a $174 million increase in capital payments in FY 2020 compared to FY 2019.

The discussions presented in the previous pages, in combination with the remainder of this proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments per discharge in FY 2020. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2020. Accordingly, based on the best available data for the 384 LTCHs in our database, we estimate that overall FY 2020 LTCH PPS payments will increase approximately $37 million relative to FY 2019 as a result of the proposed payment rates and factors presented in this proposed rule.

R. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory

review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the proposed rule, we assumed that the total number of timely pieces of correspondence on last year's proposed rule would be the number of reviewers of the proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For those reasons, and consistent with our approach in previous rulemakings (82 FR 38585; 83 FR 41777), we believe that the number of past commenters would be a fair estimate of the number of reviewers of the proposed rule. We welcome any public comments on the approach in estimating the number of entities that will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule. Therefore, for the purposes of our estimate, and consistent with our approach in previous rulemaking (82 FR 38585; 83 FR 41777), we assume that each reviewer read approximately 50 percent of the proposed rule. We welcome public comments on this assumption.

We have used the number of timely pieces of correspondence on the FY 2019 proposed rule as our estimate for the number of reviewers of this proposed rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed rule is $107.38 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 21 hours for the staff to review half of this proposed rule. For each IPPS hospital or LTCH that reviews this proposed rule, the estimated cost is $2,255 (21 hours × $107.38). Therefore, we estimate that the total cost of reviewing this proposed rule is $1,905,475 ($2,255 × 845 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a-004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in the following Table V., we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

As shown below in Table V., the net costs to the Federal Government associated with the proposed policies in this proposed rule are estimated at $4.67 billion.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2019 TO FY 2020

Category	Transfers
Annualized Monetized Transfers	$4.67 billion.
From Whom to Whom	Federal Government to IPPS Medicare Providers.

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2020 relative to FY 2019 of approximately $37 million based on the data for 384 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at: *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table VI., we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to the changes to the LTCH PPS. Table VI. provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the proposed payment rates and factors and other provisions presented in this proposed rule based on the data for the 384 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. below, the net cost to the Federal Government associated with the proposed policies for LTCHs in this proposed rule are estimated at $37 million.

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2019 LTCH PPS TO THE FY 2020 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$37 million.
From Whom to Whom	Federal Government to LTCH Medicare Providers.

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at: *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this proposed rule relating to acute care hospitals will have a significant impact on small entities as explained in this Appendix. For example, because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this proposed rule are impacts on small entities. For example, we refer readers to ''Table I.—Impact Analysis of Proposed Changes to the IPPS for Operating Costs for FY 2020.'' Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. MACs are not

considered to be small entities because they do not meet the SBA definition of a small business. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis. This proposed rule contains a range of proposed policies. It provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

For purposes of the RFA, as stated above, all hospitals and other providers and suppliers are considered to be small entities. We estimate the provisions of this proposed rule would result in an estimated $4.67 billion increase in FY 2020 payments to IPPS hospitals, primarily driven by the proposed applicable percentage increase to the IPPS rates in conjunction with other proposed payment changes including uncompensated care payments, capital payments, new technology add-on payments, and low-volume hospital payments, as discussed in section I.B. of this Appendix. As discussed in section I.J. of this Appendix, the impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2020 relative to FY 2019 of approximately $37 million. We are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we received and our responses will be presented throughout the final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (As shown in Table I. in section I.G. of this Appendix, rural IPPS hospitals with 0–49 beds and 50–99 beds are expected to experience an increase in payments from FY 2019 to FY 2020 of 4.9 percent and 3.5 percent, respectively. We refer readers to Table I. in section I.G. of this Appendix for additional information on the quantitative effects of the proposed policy changes under the IPPS for operating costs.)

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold level is approximately $154 million. This proposed rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 13175

Executive Order 13175 requires that, to the extent practicable and permitted by law, no agency shall promulgate any regulation that has tribal implications, that imposes substantial direct compliance costs on Indian tribal governments, and that is not required by statute, unless: (1) Funds necessary to pay the direct costs incurred by the Indian tribal government or the tribe in complying with the regulation are provided by the Federal Government; or (2) the agency, prior to the formal promulgation of the regulation, (A) consulted with tribal officials early in the process of developing the proposed regulation; (B) in a separately identified portion of the preamble to the regulation as it is to be issued in the **Federal Register**, provides to the Director of the Office of Management and Budget (OMB) a tribal summary impact statement, which consists of a description of the extent of the agency's prior consultation with tribal officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of tribal officials have been met; and (C) makes available to the Director of OMB any written communications submitted to the agency by tribal officials.

Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization, is eligible for payments under title XVIII of the Act, so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals under title XVIII of the Act.

This proposed rule would not mandate any requirement for Indian tribal governments, and it would not impose substantial direct compliance costs on Indian tribal governments.

VII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2020, consistent with our approach for FY 2019, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2020

A. Proposed FY 2020 Inpatient Hospital Update

As discussed in section IV.B. of the preamble to this proposed rule, for FY 2020, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the MFP adjustment may result in the applicable percentage increase being less than zero. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

In compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38587), we replaced the FY 2010-based IPPS operating and capital market baskets with the rebased and revised 2014-based IPPS operating and capital market baskets, effective beginning in FY 2018.

In this FY 2020 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2020 market basket update used to determine the applicable percentage

increase for the IPPS on IGI's fourth quarter 2018 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2018, which is estimated to be 3.2 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of this FY 2020 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2018 forecast, we are proposing an MFP adjustment of 0.5 percent for FY 2020. We also are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2020 market basket update and MFP adjustment for the final rule.

Therefore, based on IGI's fourth quarter 2018 forecast of the 2014-based IPPS market basket and the MFP adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we are proposing four possible applicable percentage increases that could be applied to the standardized amount, as shown in the table below.

PROPOSED FY 2020 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2020	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.2	3.2	3.2	3.2
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.8	-0.8
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.4	0	-2.4
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.5	-0.5	-0.5	-0.5
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.7**	**0.3**	**1.9**	**-0.5**

B. Proposed Update for SCHs and MDHs for FY 2020

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2020 applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Under current law, the MDH program is effective for discharges through September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430).

As previously mentioned, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are proposing the same four possible applicable percentage increases in the table above for the hospital-specific rate applicable to SCHs and MDHs.

C. Proposed FY 2020 Puerto Rico Hospital Update

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56939), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in

Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this proposed rule. Accordingly, for FY 2020, we are proposing to establish an applicable percentage increase of 2.7 percent to the standardized amount for hospitals located in Puerto Rico.

D. Proposed Update for Hospitals Excluded From the IPPS for FY 2020

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this proposed rule, in the FY 2018 IPPS/LTCH PPS final rule, we finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. In addition, as discussed in section IV.B. of the preamble of this proposed rule, the update to the target amount for extended neoplastic disease care hospitals for FY 2020 would be the percentage increase in the 2014-based IPPS operating market basket. Accordingly, for FY 2020, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be the FY 2020 percentage increase in the 2014-based IPPS operating market basket. For this proposed rule, the current estimate of the IPPS operating market basket percentage increase for FY 2020 is 3.2 percent.

E. Proposed Update for LTCHs for FY 2020

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to update to the LTCH PPS standard Federal payment rate for FY 2020 by 2.7 percent, consistent with the amendments to section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, the MFP adjustment). Furthermore, in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are proposing to establish an update factor of 1.027 in determining the LTCH PPS standard Federal rate for FY 2020. For LTCHs that fail to submit quality data for FY 2020, we are proposing to apply an annual update to the LTCH PPS standard Federal rate of 0.7 percent (that is, the proposed annual update for FY 2020 of 2.7 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a proposed update factor of 1.007 in determining the LTCH PPS standard Federal rate for FY 2020. (We note that, as discussed in section VII.D. of the preamble of this proposed rule, the proposed update to the LTCH PPS standard Federal payment rate of 2.7 percent for FY 2020 does not reflect any proposed budget neutrality factors.)

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update in the amount specified in current law for FY 2020. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 3.2 percent.

For FY 2020, consistent with policy set forth in section VII. of the preamble of this proposed rule, for LTCHs that submit quality data, we are recommending an update of 2.7 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2020, we are recommending an annual update to the LTCH PPS standard Federal rate of 0.7 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2019 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates by 2 percent with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the ''Hospital Value Incentive Program (HVIP).'' MedPAC stated that together, these recommendations, paired with the recommendation to eliminate the current hospital quality program incentives, would increase hospital payments by increasing the base payment rate and by increasing the average rewards hospitals receive under MedPAC's proposed Medicare HVIP.

We refer readers to the March 2019 MedPAC report, which is available for download at *www.medpac.gov,* for a complete discussion on these recommendations.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to 2 percent, with the remainder of the 2.7 percent to be used to fund its recommended Medicare HVIP, section 1886(b)(3)(B) of the Act sets the requirements for the FY 2020 applicable percentage increase. Therefore, consistent with the statute, we are proposing an applicable percentage increase for FY 2020 of 2.7 percent, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements.

Furthermore, we appreciate MedPAC's recommendation concerning a new HVIP. We agree that continual improvement motivated by quality programs is an important incentive of the IPPS. However, under current law, the inpatient hospital quality programs include the Hospital Readmissions Reduction Program, the Hospital Value-Based Purchasing Program, and the Hospital-Acquired Condition Reduction Program.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The proposed update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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