DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 412, 416, 419, 422, 423, and 424

[CMS–1613–P]

RIN 0938–AS15

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated With Submitted Data

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2015 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

In this document, we also are proposing changes to the data sources used for expansion requests for physician owned hospitals under the physician self-referral regulations; changes to the underlying authority for the requirement of an admission order for all hospital inpatient admissions and changes to require physician certification for hospital inpatient admissions only for long-stay cases and outlier cases; and changes to establish a three-level appeals process for Medicare Advantage (MA) organizations and Part D sponsors that would be applicable to CMS-identified overpayments associated with data submitted by these organizations and sponsors.

DATES: *Comment Period:* To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on September 2, 2014.

ADDRESSES: In commenting, please refer to file code CMS–1613–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

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–1613–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–1613–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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

FOR FURTHER INFORMATION, CONTACT: Marjorie Baldo, (410) 786–4617, for issues related to new CPT and Level II HCPCS codes, revised process for soliciting comments related to new Category I and III CPT codes, and exceptions to the 2 times rule.

Anita Bhatia, (410) 786–7236, for issues related to the Ambulatory Surgical Center Quality Reporting (ASCQR) Program—Program Administration and Reconsideration Issues, and for issues related to the Hospital Outpatient Quality Reporting—Program Administration, Validation, and Reconsideration Issues.

Chuck Braver, (410) 786–9379, for issues related to the CMS web posting of the OPPS & ASC payment files.

Erick Chuang, (410) 786–1816, for issues related to OPPS APC weights, OPPS data claims, geometric mean calculation, copayments, rural hospital payments, and wage index.

Dexter Dickey, (410) 786–6856, or Dorothy Myrick, (410) 786–9671, for issues related to partial hospitalization and community mental health center (CMHC) issues.

Eva Fung, (410) 786–7539, or Fiona Larbi, (410) 786–7224, or Felicia Diggs, (410) 786–1591, for issues related to HOQR and ASCQR measures issues and publication of HOQR program data issues.

Julie Gover, (410) 786–0525, for issues related to Medicare Advantage (MA) organizations and Medicare Part D sponsor overpayments.

Twi Jackson, (410) 786–1159, for issues related to device-dependent APCs, extended assessment and management composite APCs, hospital outpatient visits, inpatient procedures list, and no cost/full credit and partial credit devices.

Marina Kushnirova, (410) 786–2682, for issues related to OPPS status indicators and comment indicators.

Barry Levi, (410) 786–4529, for issues related to OPPS pass-through devices, brachytherapy sources, brachytherapy composite APC, and multiple imaging composite APCs.

John McInnes, (410) 786–0791, for issues related to comprehensive APCs, provider-based issues, packaged items/services, OPPS drugs/radiopharmaceuticals/biologicals payments, new technology intraocular

lenses (NTIOLs), and ambulatory surgical center (ASC) payments.

David Rice, (410) 786–6004, for issues related to blood and blood products, cancer hospital payments, conversion factor, cost-to-charge ratios (CCRs), and outlier payments.

Daniel Schroder, (410) 786–7452, for issues related to physician certification of hospital inpatient services.

Carol Schwartz, (410) 786–0576, for issues related to the Advisory Panel on Hospital Outpatient Payment (HOP Panel).

Teresa Walden, (410) 786–3755, or Patricia Taft, (410) 786–4561, for issues related to the physician self-referral law/physician-owned hospital expansion exception process.

Marjorie Baldo, (410) 786–4617, for all other issues related to hospital outpatient and ambulatory surgical center payments not previously identified.

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 Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is also 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/*.

Addenda Available Only Through the Internet on the CMS Web site

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS Web site. The Addenda relating to the OPPS are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The Addenda relating to the ASC payment system are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html*.

Alphabetical List of Acronyms Appearing in This Federal Register Document

AHA American Hospital Association
AMA American Medical Association
APC Ambulatory Payment Classification
ASC Ambulatory surgical center
ASCQR Ambulatory Surgical Center Quality Reporting
ASP Average sales price
AWP Average wholesale price
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Pub. L. 106–113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106–554
BLS Bureau of Labor Statistics
CAH Critical access hospital
CAP Competitive Acquisition Program
C–APC Comprehensive Ambulatory Payment Classification
CASPER Certification and Survey Provider Enhanced Reporting
CAUTI Catheter-associated urinary tract infection
CBSA Core-Based Statistical Area
CCI Correct Coding Initiative
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDC Centers for Disease Control and Prevention
CEO Chief executive officer
CERT Comprehensive Error Rate Testing
CFR Code of Federal Regulations
CLFS Clinical Laboratory Fee Schedule
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services
CPI–U Consumer Price Index for All Urban Consumers
CPT Current Procedural Terminology (copyrighted by the American Medical Association)
CQM Clinical quality measure
CR Change request
CSAC Consensus Standards Approval Committee
CY Calendar year
DFO Designated Federal Official
DRA Deficit Reduction Act of 2005, Pub. L. 109–171
DRG Diagnosis-Related Group
DSH Disproportionate share hospital
EACH Essential access community hospital
eCQM Electronically specified clinical quality measure
ECT Electroconvulsive therapy
ED Emergency department
E/M Evaluation and management
EHR Electronic health record
ESRD End-stage renal disease
FACA Federal Advisory Committee Act, Pub. L. 92–463
FDA Food and Drug Administration
FFS [Medicare] Fee-for-service
FY Fiscal year
FFY Federal fiscal year
GAO Government Accountability Office
HAI Healthcare-associated infection
HCERA Health Care and Education Reconciliation Act of 2010, Pub. L. 111–152
HCPCS Healthcare Common Procedure Coding System
HCRIS Healthcare Cost Report Information System
HEU Highly enriched uranium
HIPAA Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191
HITECH Health Information Technology for Economic and Clinical Health [Act] (found in the American Recovery and Reinvestment Act of 2009, Pub. L. 111–5)
HOP Hospital Outpatient Payment [Panel]
HOPD Hospital outpatient department
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD Implantable cardioverter defibrillator
ICU Intensive care unit
IHS Indian Health Service
IMRT Intensity Modulated Radiation Therapy
I/OCE Integrated Outpatient Code Editor
IOL Intraocular lens
IOM Institute of Medicine
IORT Intraoperative radiation treatment
IPPS [Hospital] Inpatient Prospective Payment System
IQR [Hospital] Inpatient Quality Reporting
LDR Low dose rate
LOS Length of stay
LTCH Long-term care hospital
MAC Medicare Administrative Contractor
MAP Measure Application Partnership
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multifactor productivity
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006, Pub. L. 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110–275
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Pub. L. 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. 110–173
MPFS Medicare Physician Fee Schedule
MRA Magnetic resonance angiography

MRI Magnetic resonance imaging
MSA Metropolitan Statistical Area
NCCI National Correct Coding Initiative
NHSN National Healthcare Safety Network
NQF National Quality Forum
NTIOL New technology intraocular lens
NUBC National Uniform Billing Committee
OACT [CMS] Office of the Actuary
OBRA Omnibus Budget Reconciliation Act of 1996, Pub. L. 99–509
OIG [HHS] Office of the Inspector General
OMB Office of Management and Budget
OPD [Hospital] Outpatient Department
OPO Organ Procurement Organization
OPPS [Hospital] Outpatient Prospective Payment System
OPSF Outpatient Provider-Specific File
OQR [Hospital] Outpatient Quality Reporting
OT Occupational therapy
PBD Provider-Based Department
PCR Payment-to-cost ratio
PE Practice expense
PEPPER Program for Evaluating Payment Patterns Electronic Report
PHP Partial hospitalization program
PHS Public Health Service [Act], Pub. L. 96–88
PPI Producer Price Index
PPS Prospective payment system
PQRS Physician Quality Reporting System
PT Physical therapy
QDC Quality data code
QIO Quality Improvement Organization
RFA Regulatory Flexibility Act
RTI Research Triangle Institute, International
RVU Relative value unit
SCH Sole community hospital
SCOD Specified covered outpatient drugs
SI Status indicator
SIR Standardized infection ratio
SLP Speech-language pathology
SNF Skilled nursing facility
SRS Stereotactic radiosurgery
TEP Technical Expert Panel
TMS Transcranial Magnetic Stimulation Therapy
TOPs Transitional Outpatient Payments
UR Utilization review
USPSTF United States Preventive Services Task Force
UTI Urinary tract infection
VBP Value-based purchasing
WAC Wholesale acquisition cost

Table of Contents

Regulation Text

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we are proposing to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments and Ambulatory Surgical Centers (ASCs) beginning January 1, 2015. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the relative payment weights and the conversion factor for services payable under the Outpatient Prospective Payment System (OPPS). Under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

In this document, we also are proposing changes to the data sources used for expansion requests for physician owned hospitals under the physician self-referral regulations; changes to the underlying authority for the requirement of an admission order for all hospital inpatient admissions and changes to require physician certification for hospital inpatient admissions only for long-stay cases and outlier cases; and changes to establish a three-level appeals process for Medicare Advantage (MA) organizations and Part D sponsors that would be applicable to CMS-identified overpayments associated with data submitted by these organizations and sponsors.

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2015, we are proposing to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.1 percent. This proposed increase is based on the proposed hospital inpatient market basket percentage increase of 2.7 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.4 percentage points, and minus a 0.2 percentage point adjustment required by the Affordable Care Act. Under this proposed rule, we estimate that proposed total payments for CY 2015, including beneficiary cost-sharing, to the approximate 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), will be approximately $56.5 billion, an increase of approximately $5.2 billion compared to CY 2014 payments, or $800 million excluding our estimated changes in enrollment, utilization, and case-mix.

We are proposing to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

- *Rural Adjustment:* We are proposing to continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This adjustment will apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost.

- *Cancer Hospital Payment Adjustment:* For CY 2015, we are proposing to continue to provide additional payments to cancer hospitals so that the cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS

hospitals using the most recently submitted or settled cost report data. Based on those data, a target PCR of 0.89 will be used to determine the proposed CY 2015 cancer hospital payment adjustment to be paid at cost report settlement. That is, the proposed payment adjustments will be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals:* For CY 2015, proposed payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status would be set at the statutory default of average sales price (ASP) plus 6 percent.

• *Packaging Policies:* We are proposing to conditionally package certain ancillary services when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service. The initial set of services proposed to be packaged under this ancillary service policy are the services assigned to APCs having a proposed APC geometric mean cost (prior to application of status indicator Q1) of less than or equal to $100. This proposed $100 geometric mean cost limit for the APC is part of the methodology of establishing an initial set of conditionally packaged ancillary service APCs, and is not meant to represent a threshold above which a given ancillary service would not be packaged, but as a basis for selecting an initial set of APCs that would likely be updated and expanded in future years.

• *Implementation of Comprehensive APCs:* For CY 2015, we are proposing to implement, with several modifications, the policy for comprehensive APCs that was finalized in the CY 2014 OPPS/ASC final rule with comment period effective January 1, 2015. We are proposing to continue to define the services assigned to comprehensive APCs as primary services, and to define a comprehensive APC as a classification for the provision of a primary service and all adjunctive services and supplies provided to support the delivery of the primary service. We would continue to consider the entire hospital stay, defined as all services reported on the hospital claim reporting the primary service, to be one comprehensive service for the provision of a primary service into which all other services appearing on the claim would be packaged. This would result in a single Medicare payment and a single beneficiary copayment under the OPPS for the comprehensive service based on all included charges on the claim.

We are proposing a total of 28 comprehensive APCs for CY 2015, including all of the device-dependent APCs remaining after some restructuring and consolidation of these APCs and two comprehensive APCs for other procedures that are either largely device dependent or represent single session services with multiple components (single-session cranial stereotactic radiosurgery and intraocular telescope implantation). We are proposing to modify the complexity adjustment criteria finalized last year, proposing lower volume and cost threshold criteria for complexity adjustments. Finally, we are proposing to package all add-on codes furnished as part of a comprehensive service, which is consistent with our general add-on code packaging policy. However, the add-on codes assigned to the CY 2014 device-dependent APCs would be being evaluated with a primary service for a potential complexity adjustment.

• *Ambulatory Surgical Center Payment Update:* For CY 2015, we are proposing to increase payment rates under the ASC payment system by 1.2 percent. This proposed increase is based on a projected CPI–U update of 1.7 percent minus a multifactor productivity adjustment required by the Affordable Care Act that is projected to be 0.5 percent. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2015 would be approximately $4.086 billion, an increase of approximately $243 million compared to estimated CY 2014 payments.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are proposing to add one claims-based quality measure for the CY 2017 payment determination and subsequent years. We are proposing to refine the criteria for determining when to remove a measure because it is ''topped-out'' and we are proposing to remove three measures due to ''topped-out'' status. In addition, we are updating several previously adopted measures. We are proposing to exclude one previously adopted measure from the measure set for the CY 2016 payment determination and to change this measure from required to voluntary for the CY 2017 payment determination and subsequent years. Hospitals would not be subject to payment reductions with respect to this measure. In addition, we are proposing to formalize a review and corrections period for chart-abstracted measures. We also are proposing updates to validation procedures and changes to regulation text to correct typographical errors. Finally, we are clarifying how we refer to the extraordinary circumstances extensions or exemptions process.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are proposing to adopt one new quality measure for the CY 2017 payment determination and subsequent years. The measure would be computed using Medicare claims data and would not impose any additional burden on ASC facilities. We also are proposing that one measure previously adopted for the CY 2016 and subsequent years' payment determinations be excluded from the CY 2016 measure set and that this measure be voluntarily reported for the CY 2017 payment determination and subsequent years, rather than mandatorily reported. We would not subject ASCs to payment reductions with respect to this measure for the CY 2016 payment determination or during the period of voluntary reporting. In addition, we are proposing to define the data collection timeframes and submission deadlines for one previously adopted measure, noting the delayed data collection of two measures for the CY 2016 payment determination, and clarifying how we refer to the extraordinary circumstances extensions or exemptions process.

3. Summary of Costs and Benefits

In sections XXI. and XXII. of this proposed rule, we set forth a detailed analysis of the regulatory and federalism impacts that the proposed changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the OPPS Update

(1) Impacts of All Proposed OPPS Changes

Table 52 in section XXI. of this proposed rule displays the distributional impact all the proposed OPPS changes on various groups of hospitals and CMHCs for CY 2015 compared to all estimated OPPS payments in CY 2014. We estimate that the proposed policies in this proposed rule would result in a 2.2 percent overall increase in OPPS payments to providers. We estimate that proposed total OPPS payments for CY 2015, including beneficiary cost-sharing, to the approximate 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), will be approximately $56.5 billion, an increase of approximately $5.2 billion compared to CY 2014 payments, or $800 million, excluding

our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our proposed OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure that we adopted beginning in CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate a −1.6 percent decrease in CY 2015 payments to CMHCs relative to their CY 2014 payments.

(2) Impacts of the Proposed Updated Wage Indexes

We estimate that our proposal to update the wage indexes and apply the frontier State wage index, including changes resulting from the proposed adoption of the new OMB labor market area delineations and the proposed transitional 1-year, 50/50 blended wage index, would have a positive impact on payments to hospitals.

(3) Impacts of the Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our proposed CY 2015 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural and cancer hospital payment adjustments, and the proposed adjustment amounts do not significantly impact the budget neutrality adjustments for these proposed policies.

(4) Impacts of the Proposed OPD Fee Schedule Increase Factor

We estimate that, for most hospitals, the application of the proposed OPD fee schedule increase factor of 2.1 percent to the conversion factor for CY 2015 would mitigate the small negative impacts of the budget neutrality adjustments. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that rural and urban hospitals would experience increases of approximately 2.1 percent for urban hospitals and 2.4 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals will receive similar increases.

b. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The proposed percentage change in estimated total payments by specialty groups under the proposed CY 2015 payment rates compared to estimated CY 2014 payment rates ranges between −3.0 percent for cardiovascular system procedures and 12 percent for hematologic and lymphatic system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our proposed CY 2015 policies to significantly affect the number of hospitals that do not receive a full annual payment update.

d. Impacts of the ASCQR Program

We do not expect our proposed CY 2015 proposed policies to significantly affect the number of ASCs that do not receive a full annual payment update.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR Parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (These two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; and the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013.

Under the OPPS, we pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals include: Maryland hospitals, but only for services that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act; critical access hospitals (CAHs); hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Pub. L. 106–113, and redesignated by section 202(a)(2) of Pub. L. 106–113, requires that we consult with an external advisory panel of experts to annually review the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act and section 222 of the Public Health Service (PHS) Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the PHS Act which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel, or the Panel). The Panel is not restricted to using data compiled by CMS, and in conducting its review it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the HOP Panel, at that time named the APC Panel. This expert panel, which may be composed of up to 19 appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise), reviews clinical data and advises CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that: The Panel continues to be technical in nature; is governed by the provisions of the FACA; may convene up to three meetings per year; has a Designated Federal Official (DFO); and is chaired by a Federal Official designated by the Secretary. The current charter was amended on November 15, 2011 and the Panel was renamed to reflect expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and therefore to add CAHs to its membership.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage*.

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on March 10, 2014. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations

for Panel membership and to announce new members.

The Panel has established an operational structure that, in part, currently includes the use of three subcommittees to facilitate its required review process. The three current subcommittees are the Data Subcommittee, the Visits and Observation Subcommittee, and the Subcommittee for APC Groups and Status Indicator (SI) Assignments.

The Data Subcommittee is responsible for studying the data issues confronting the Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS (for example, APC configurations and APC relative payment weights). The Subcommittee for APC Groups and SI Assignments advises the Panel on the following issues: The appropriate SIs to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid; and the appropriate APC placement of HCPCS codes regarding services for which separate payment is made.

Each of these subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the March 2014 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the March 2014 Panel meeting are included in the sections of this proposed rule that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS Web site mentioned earlier in this section, and the FACA database at: *http://fido.gov/facadatabase/public.asp*.

F. Public Comments Received on the CY 2014 OPPS/ASC Final Rule With Comment Period

We received 490 timely pieces of correspondence on the CY 2014 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on December 10, 2013 (78 FR 74826), some of which contained comments on the interim APC assignments and/or status indicators of new or replacement HCPCS codes (identified with comment indicator ''NI'' in Addenda B, AA, and BB to that final rule). Summaries of the public comments on new or replacement codes will be set forth in the CY 2015 final rule with comment period under the appropriate subject-matter headings. However, we are summarizing the public comments on the CY 2014 OPPS/ASC final rule with comment period regarding comprehensive APCs in this proposed rule rather than the CY 2015 final rule with comment period, as we are proposing several methodological changes in response to these public comments.

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For the CY 2015 OPPS, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2015, and before January 1, 2016 (CY 2015), using the same basic methodology that we described in the CY 2014 OPPS/ASC final rule with comment period. That is, we are proposing to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights. Therefore, for the purpose of recalibrating the proposed APC relative payment weights for CY 2015, we used approximately 149 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for hospital outpatient department services furnished on or after January 1, 2013, and before January 1, 2014. For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for this CY 2015 OPPS/ASC proposed rule on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Of the approximately 149 million final action claims for services provided in hospital outpatient settings used to calculate the CY 2015 OPPS payment rates for this proposed rule, approximately 119 million claims were the type of bill potentially appropriate for use in setting rates for OPPS services (but did not necessarily contain services payable under the OPPS). Of the approximately 119 million claims, approximately 5 million claims were not for services paid under the OPPS or were excluded as not appropriate for use (for example, erroneous cost-to-charge ratios (CCRs) or no HCPCS codes reported on the claim). From the remaining approximately 114 million claims, we created approximately 94 million single records, of which approximately 46 million were ''pseudo'' single or ''single session'' claims (created from approximately 21 million multiple procedure claims using the process we discuss later in this section). Approximately 1 million claims were trimmed out on cost or units in excess of ± 3 standard deviations from the geometric mean, yielding approximately 94 million single bills for ratesetting. As described in section II.A.2. of this proposed rule, our data development process is designed with the goal of using appropriate cost information in setting the APC relative payment weights. The bypass process is described in section II.A.1.b. of this proposed rule. This section discusses how we develop ''pseudo'' single procedure claims (as defined below), with the intention of using more appropriate data from the available claims. In some cases, the bypass process allows us to use some portion of the submitted claim for cost estimation purposes, while the remaining information on the claim continues to be unusable. Consistent with the goal of using appropriate information in our data development process, we only use claims (or portions of each claim) that are appropriate for ratesetting purposes.

The proposed APC relative weights and payments for CY 2015 in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) were calculated using claims from CY 2013 that were processed through December 31, 2013. While prior to CY 2013 we historically based the payments on median hospital costs for services in the APC groups, beginning with the CY 2013 OPPS, we established the cost-based relative payment weights for the OPPS using geometric mean costs, as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271). For the CY 2015 OPPS, we are proposing to use this same methodology, basing payments on

geometric mean costs. Under this methodology, we select claims for services paid under the OPPS and match these claims to the most recent cost report filed by the individual hospitals represented in our claims data. We continue to believe that it is appropriate to use the most current full calendar year claims data and the most recently submitted cost reports to calculate the relative costs underpinning the APC relative payment weights and the CY 2015 payment rates.

b. Proposed Use of Single and Multiple Procedure Claims

For CY 2015, in general, we are proposing to continue to use single procedure claims to set the costs on which the APC relative payment weights are based. We generally use single procedure claims to set the estimated costs for APCs because we believe that the OPPS relative weights on which payment rates are based should be derived from the costs of furnishing one unit of one procedure and because, in many circumstances, we are unable to ensure that packaged costs can be appropriately allocated across multiple procedures performed on the same date of service.

It is generally desirable to use the data from as many claims as possible to recalibrate the APC relative payment weights, including those claims for multiple procedures. As we have for several years, we are proposing to continue to use date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims. Through bypassing specified codes that we believe do not have significant packaged costs, we are able to use more data from multiple procedure claims. In many cases, this enables us to create multiple ''pseudo'' single procedure claims from claims that were submitted as multiple procedure claims spanning multiple dates of service, or claims that contained numerous separately paid procedures reported on the same date on one claim. We refer to these newly created single procedure claims as ''pseudo'' single procedure claims. The history of our use of a bypass list to generate ''pseudo'' single procedure claims is well documented, most recently in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74849 through 74851). In addition, for CY 2008 (72 FR 66614 through 66664), we increased packaging and created the first composite APCs, and continued those policies through CY 2014. Increased packaging and creation of composite APCs also increased the number of bills that we were able to use for ratesetting by enabling us to use claims that contained multiple major procedures that previously would not have been usable. Further, for CY 2009, we expanded the composite APC model to one additional clinical area, multiple imaging services (73 FR 68559 through 68569), which also increased the number of bills we were able to use in developing the OPPS relative weights on which payments are based. We have continued the composite APCs for multiple imaging services through CY 2014, and we are proposing to continue this policy for CY 2015. We refer readers to section II.A.2.f. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74910 through 74925) for a discussion of the use of claims in modeling the costs for composite APCs and to section II.A.3. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925 through 74948) for a discussion of our packaging policies for CY 2014. In addition, we are proposing to establish additional packaging policies for the CY 2015 OPPS, as discussed in section II.A.3. of this proposed rule.

We are proposing to continue to apply these processes to enable us to use as much claims data as possible for ratesetting for the CY 2015 OPPS. This methodology enabled us to create, for this proposed rule, approximately 46 million ''pseudo'' single procedure claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.f.(5) of this proposed rule for further discussion), to add to the approximately 48 million ''natural'' single procedure claims.

For CY 2015, we are proposing to bypass 227 HCPCS codes that are identified in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site). Since the inception of the bypass list, which is the list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims, we have calculated the percent of ''natural'' single bills that contained packaging for each HCPCS code and the amount of packaging on each ''natural'' single bill for each code. Each year, we generally retain the codes on the previous year's bypass list and use the updated year's data (for CY 2015, data available for the March 10, 2014 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) from CY 2013 claims processed through September 30, 2013, and CY 2012 claims data processed through June 30, 2013, used to model the payment rates for CY 2014) to determine whether it would be appropriate to add additional codes to the previous year's bypass list. For CY 2015, we are proposing to continue to bypass all of the HCPCS codes on the CY 2014 OPPS bypass list, with the exception of HCPCS codes that we are proposing to delete for CY 2015, which are listed in Table 1 of this proposed rule. We also are proposing to remove HCPCS codes that are not separately paid under the OPPS because the purpose of the bypass list is to obtain more data for those codes relevant to ratesetting. Some of the codes we are proposing to remove from the CY 2015 bypass list are affected by the CY 2015 proposed packaging policy, discussed in section II.A.3. of this proposed rule. In addition, we are proposing to add to the bypass list for CY 2015 HCPCS codes not on the CY 2014 bypass list that, using either the CY 2014 final rule data (CY 2012 claims) or the March 10, 2014 Panel data (first 9 months of CY 2013 claims), met the empirical criteria for the bypass list that are summarized below. Finally, to remain consistent with the CY 2015 proposal to continue to develop OPPS relative payment weights based on geometric mean costs, we also are proposing that the packaged cost criterion continue to be based on the geometric mean cost. The entire list proposed for CY 2015 (including the codes that remain on the bypass list from prior years) is open to public comment in this CY 2015 OPPS/ASC proposed rule. Because we must make some assumptions about packaging in the multiple procedure claims in order to assess a HCPCS code for addition to the bypass list, we assumed that the representation of packaging on ''natural'' single procedure claims for any given code is comparable to packaging for that code in the multiple procedure claims. The proposed criteria for the bypass list are:

- There are 100 or more ''natural'' single procedure claims for the code. This number of single procedure claims ensures that observed outcomes are sufficiently representative of packaging that might occur in the multiple claims.
- Five percent or fewer of the ''natural'' single procedure claims for the code have packaged costs on that single procedure claim for the code. This criterion results in limiting the amount of packaging being redistributed to the separately payable procedures remaining on the claim after the bypass code is removed and ensures that the costs associated with the bypass code represent the cost of the bypassed service.
- The geometric mean cost of packaging observed in the ''natural'' single procedure claims is equal to or less than $55. This criterion also limits

the amount of error in redistributed costs. During the assessment of claims against the bypass criteria, we do not know the dollar value of the packaged cost that should be appropriately attributed to the other procedures on the claim. Therefore, ensuring that redistributed costs associated with a bypass code are small in amount and volume protects the validity of cost estimates for low cost services billed with the bypassed service.

We note that, as we did for CY 2014, we are proposing to continue to establish the CY 2015 OPPS relative payment weights based on geometric mean costs. To remain consistent in the metric used for identifying cost patterns, we are proposing to use the geometric mean cost of packaging to identify potential codes to add to the bypass list.

In response to public comments on the CY 2010 OPPS/ASC proposed rule requesting that the packaged cost threshold be updated, we considered whether it would be appropriate to update the $50 packaged cost threshold for inflation when examining potential bypass list additions. As discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60328), the real value of this packaged cost threshold criterion has declined due to inflation, making the packaged cost threshold more restrictive over time when considering additions to the bypass list. Therefore, adjusting the threshold by the market basket increase would prevent continuing decline in the threshold's real value. Based on the same rationale described for the CY 2014 OPPS/ASC final rule with comment period (78 FR 74838), we are proposing for CY 2015 to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2014 market basket increase of 1.7 percent to the prior nonrounded dollar threshold of $54.73 (78 FR 74838), we determined that the threshold remains for CY 2015 at $55 ($55.66 rounded to $55, the nearest $5 increment). Therefore, we are proposing to set the geometric mean packaged cost threshold on the CY 2013 claims at $55 for a code to be considered for addition to the CY 2015 OPPS bypass list.

- The code is not a code for an unlisted service. Unlisted codes do not describe a specific service, and thus their costs would not be appropriate for bypass list purposes.

In addition, we are proposing to continue to include on the bypass list HCPCS codes that CMS medical advisors believe have minimal associated packaging based on their clinical assessment of the complete CY 2015 OPPS proposal. Some of these codes were identified by CMS medical advisors and some were identified in prior years by commenters with specialized knowledge of the packaging associated with specific services. We also are proposing to continue to include certain HCPCS codes on the bypass list in order to purposefully direct the assignment of packaged costs to a companion code where services always appear together and where there would otherwise be few single procedure claims available for ratesetting. For example, we have previously discussed our reasoning for adding HCPCS code G0390 (Trauma response team associated with hospital critical care service) to the bypass list (73 FR 68513).

As a result of the multiple imaging composite APCs that we established in CY 2009, the program logic for creating ''pseudo'' single procedure claims from bypassed codes that are also members of multiple imaging composite APCs changed. When creating the set of ''pseudo'' single procedure claims, claims that contain ''overlap bypass codes'' (those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs) were identified first. These HCPCS codes were then processed to create multiple imaging composite ''single session'' bills, that is, claims containing HCPCS codes from only one imaging family, thus suppressing the initial use of these codes as bypass codes. However, these ''overlap bypass codes'' were retained on the bypass list because, at the end of the ''pseudo'' single processing logic, we reassessed the claims without suppression of the ''overlap bypass codes'' under our longstanding ''pseudo'' single process to determine whether we could convert additional claims to ''pseudo'' single procedure claims. (We refer readers to section II.A.2.b. of this proposed rule for further discussion of the treatment of ''overlap bypass codes.'') This process also created multiple imaging composite ''single session'' bills that could be used for calculating composite APC costs. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site).

Addendum N to this proposed rule (which is available via the Internet on the CMS Web site) includes the proposed list of bypass codes for CY 2015. The proposed list of bypass codes contains codes that were reported on claims for services in CY 2013 and, therefore, includes codes that were in effect in CY 2013 and used for billing but were deleted for CY 2014. We retained these deleted bypass codes on the proposed CY 2015 bypass list because these codes existed in CY 2013 and were covered OPD services in that period, and CY 2013 claims data are used to calculate CY 2015 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that were members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add for CY 2015 are identified by asterisks (*) in the fourth column of Addendum N.

Table 1 below contains the list of codes that we are proposing to remove from the CY 2015 bypass list because these codes were either deleted from the HCPCS before CY 2013 (and therefore were not covered OPD services in CY 2013) or are not separately payable codes under the proposed CY 2015 OPPS because these codes are not used for ratesetting through the bypass process. The list of codes proposed for removal from the bypass list includes those that would be affected by the proposed CY 2015 OPPS packaging policy described in section II.A.3. of this proposed rule.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2015 BYPASS LIST

HCPCS Code	HCPCS Short descriptor
11056	Trim skin lesions 2 to 4.
11300	Shave skin lesion 0.5 cm/<.
11301	Shave skin lesion 0.6–1.0 cm.
11719	Trim nail(s) any number.
11720	Debride nail 1–5.
11721	Debride nail 6 or more.
17000	Destruct premalg lesion.
17110	Destruct b9 lesion 1–14.
29240	Strapping of shoulder.
29260	Strapping of elbow or wrist.
29280	Strapping of hand or finger.
29520	Strapping of hip.
29530	Strapping of knee.
51741	Electro-uroflowmetry first.
51798	Us urine capacity measure.
53601	Dilate urethra stricture.
53661	Dilation of urethra.
54240	Penis study.
67820	Revise eyelashes.
69210	Remove impacted ear wax uni.
69220	Clean out mastoid cavity.
70030	X-ray eye for foreign body.
70100	X-ray exam of jaw <4views.
70110	X-ray exam of jaw 4/> views.
70120	X-ray exam of mastoids.
70130	X-ray exam of mastoids.
70140	X-ray exam of facial bones.
70150	X-ray exam of facial bones.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2015 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
70160	X-ray exam of nasal bones.
70200	X-ray exam of eye sockets.
70210	X-ray exam of sinuses.
70220	X-ray exam of sinuses.
70240	X-ray exam pituitary saddle.
70250	X-ray exam of skull.
70260	X-ray exam of skull.
70320	Full mouth x-ray of teeth.
70328	X-ray exam of jaw joint.
70330	X-ray exam of jaw joints.
70355	Panoramic x-ray of jaws.
70360	X-ray exam of neck.
71021	Chest x-ray frnt lat lordotc.
71022	Chest x-ray frnt lat oblique.
71023	Chest x-ray and fluoroscopy.
71030	Chest x-ray 4/≤ views.
71035	Chest x-ray special views.
71100	X-ray exam ribs uni 2 views.
71101	X-ray exam unilat ribs/chest.
71110	X-ray exam ribs bil 3 views.
71111	X-ray exam ribs/chest4/> vws.
71120	X-ray exam breastbone 2/>vws.
71130	X-ray strenoclavic jt 3/>vws.
72020	X-ray exam of spine 1 view.
72040	X-ray exam neck spine 2–3 vw.
72050	X-ray exam neck spine 4/5vws.
72052	X-ray exam neck spine 6/>vws.
72069	X-ray exam trunk spine stand.
72070	X-ray exam thorac spine 2vws.
72072	X-ray exam thorac spine 3vws.
72074	X-ray exam thorac spine4/>vw.
72080	X-ray exam trunk spine 2 vws.
72090	X-ray exam scloiosis erect.
72100	X-ray exam l-s spine ⅔ vws.
72110	X-ray exam l-2 spine 4/>vws.
72114	X-ray exam l-s spine bending.
72120	X-ray bend only l-s spine.
72170	X-ray exam of pelvis.
72190	X-ray exam of pelvis.
72202	X-ray exam si joints 3/< vws.
72220	X-ray exam sacrum tailbone.
73000	X-ray exam of collar bone.
73010	X-ray exam of shoulder blade.
73020	X-ray exam of shoulder.
73030	X-ray exam of shoulder.
73050	X-ray exam of shoulders.
73060	X-ray exam of humerus.
73070	X-ray exam of elbow.
73080	X-ray exam of elbow.
73090	X-ray exam of forearm.
73100	X-ray exam of wrist.
73110	X-ray exam of wrist.
73120	X-ray exam of hand.
73130	X-ray exam of hand.
73140	X-ray exam of finger(s).
73510	X-ray exam of hip.
73520	X-ray exam of hips.
73540	X-ray exam of pelvis & hips.
73550	X-ray exam of thigh.
73560	X-ray exam of knee 1 or 2.
73562	X-ray exam of knee 3.
73564	X-ray exam knee 4 or more.
73565	X-ray exam of knees.
73590	X-ray exam of lower leg.
73600	X-ray exam of ankle.
73610	X-ray exam of ankle.
73620	X-ray exam of foot.
73630	X-ray exam of foot.
73650	X-ray exam of heel.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2015 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
73660	X-ray exam of toe(s).
74000	X-ray exam of abdomen.
74010	X-ray exam of abdomen.
74020	X-ray exam of abdomen.
74022	X-ray exam series abdomen.
76100	X-ray exam of body section.
76510	Ophth us b & quant a.
76514	Echo exam of eye thickness.
76516	Echo exam of eye.
76519	Echo exam of eye.
76645	Us exam breast(s).
76816	Ob us follow-up per fetus.
76882	Us xtr non-vasc lmtd.
76970	Ultrasound exam follow-up.
76977	Us bone density measure.
77072	X-rays for bone age.
77073	X-rays bone length studies.
77074	X-rays bone survey limited.
77076	X-rays bone survey infant.
77077	Joint survey single view.
77078	Ct bone density axial.
77079	Ct bone density peripheral.
77080	Dxa bone density axial.
77081	Dxa bone density/peripheral.
77082	Dxa bone density vert fx.
77083	Radiographic absorptiometry.
80500	Lab pathology consultation.
80502	Lab pathology consultation.
85097	Bone marrow interpretation.
86510	Histoplasmosis skin test.
86850	Rbc antibody screen.
86870	Rbc antibody identification.
86880	Coombs test direct.
86885	Coombs test indirect qual.
86886	Coombs test indirect titer.
86900	Blood typing abo.
86901	Blood typing rh (d).
86904	Blood typing patient serum.
86905	Blood typing rbc antigens.
86906	Blood typing rh phenotype.
86930	Frozen blood prep.
86970	Rbc pretx incubatj w/chemicl.
86977	Rbc serum pretx incubj/inhib.
88104	Cytopath fl nongyn smears.
88106	Cytopath fl nongyn filter.
88107	Cytopath fl nongyn sm/fltr.
88108	Cytopath concentrate tech.
88112	Cytopath cell enhance tech.
88120	Cytp urne 3–5 probes ea spec.
88160	Cytopath smear other source.
88161	Cytopath smear other source.
88162	Cytopath smear other source.
88172	Cytp dx eval fna 1st ea site.
88173	Cytopath eval fna report.
88182	Cell marker study.
88184	Flowcytometry/tc 1 marker.
88189	Flowcytometry/read 16 & >.
88300	Surgical path gross.
88302	Tissue exam by pathologist.
88304	Tissue exam by pathologist.
88305	Tissue exam by pathologist.
88307	Tissue exam by pathologist.
88312	Special stains group 1.
88313	Special stains group 2.
88321	Microslide consultation.
88323	Microslide consultation.
88325	Comprehensive review of data.
88329	Path consult introp.
88331	Path consult intraop 1 bloc.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2015 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
88342	Immunohisto antibody slide.
88346	Immunofluorescent study.
88347	Immunofluorescent study.
88348	Electron microscopy.
88358	Analysis tumor.
88360	Tumor immunohistochem/manual.
88361	Tumor immunohistochem/comput.
88365	Insitu hybridization (fish).
88368	Insitu hybridization manual.
88385	Eval molecul probes 51–250.
88386	Eval molecul probes 251–500.
89049	Chct for mal hyperthermia.
89220	Sputum specimen collection.
89230	Collect sweat for test.
89240	Pathology lab procedure.
92020	Special eye evaluation.
92025	Corneal topography.
92060	Special eye evaluation.
92081	Visual field examination(s).
92082	Visual field examination(s).
92083	Visual field examination(s).
92133	Cmptr ophth img optic nerve.
92134	Cptr ophth dx img post segmt.
92136	Ophthalmic biometry.
92225	Special eye exam initial.
92226	Special eye exam subsequent.
92230	Eye exam with photos.
92250	Eye exam with photos.
92285	Eye photography.
92286	Internal eye photography.
92520	Laryngeal function studies.
92541	Spontaneous nystagmus test.
92542	Positional nystagmus test.
92550	Tympanometry & reflex thresh.
92552	Pure tone audiometry air.
92553	Audiometry air & bone.
92555	Speech threshold audiometry.
92556	Speech audiometry complete.
92557	Comprehensive hearing test.
92567	Tympanometry.
92570	Acoustic immitance testing.
92582	Conditioning play audiometry.
92603	Cochlear implt f/up exam 7/>.
92604	Reprogram cochlear implt 7/>.
92626	Eval aud rehab status.
93005	Electrocardiogram tracing.
93017	Cardiovascular stress test.
93225	Ecg monit/reprt up to 48 hrs.
93226	Ecg monit/reprt up to 48 hrs.
93270	Remote 30 day ecg rev/report.
93278	Ecg/signal-averaged.
93279	Pm device progr eval sngl.
93280	Pm device progr eval dual.
93281	Pm device progr eval multi.
93282	Icd device progr eval 1 sngl.
93283	Icd device progr eval dual.
93284	Icd device progr eval mult.
93285	Ilr device eval progr.
93288	Pm device eval in person.
93289	Icd device interrogate.
93290	Icm device eval.
93291	Ilr device interrogate.
93292	Wcd device interrogate.
93293	Pm phone r-strip device eval.
93296	Pm/icd remote tech serv.
93299	Icm/ilr remote tech serv.
93701	Bioimpedance cv analysis.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2015 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
93786	Ambulatory bp recording.
93788	Ambulatory bp analysis.
93875	Extracranial study.
94015	Patient recorded spirometry.
94690	Exhaled air analysis.
95803	Actigraphy testing.
95869	Muscle test thor paraspinal.
95900	Motor nerve conduction test.
95921	Autonomic nrv parasym inervj.
95970	Analyze neurostim no prog.
96900	Ultraviolet light therapy.
96910	Photochemotherapy with uv-b.
96912	Photochemotherapy with uv-a.
96921	Laser tx skin 250–500 sq cm.
98925	Osteopath manj 1–2 regions.
98926	Osteopath manj 3–4 regions.
98927	Osteopath manj 5–6 regions.
98928	Osteopath manj 7–8 regions.
98929	Osteopath manj 9–10 regions.
98940	Chiropract manj 1–2 regions.
98941	Chiropract manj 3–4 regions.
98942	Chiropractic manj 5 regions.
G0127	Trim nail(s).
G0130	Single energy x-ray study.
G0166	Extrnl counterpulse, per tx.
G0239	Oth resp proc, group.
G0389	Ultrasound exam aaa screen.
G0404	Ekg tracing for initial prev.
G0424	Pulmonary rehab w exer.
Q0091	Obtaining screen pap smear.

c. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2015, we are proposing to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2015 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2013 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2012. For the CY 2015 OPPS proposed rates, we used the set of claims processed during CY 2013. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2013 (the year of claims data we used to calculate the proposed CY 2015 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2013 Data Specifications Manual.

In accordance with our longstanding policy, we calculated CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculated CCRs was the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.d.(2) of this proposed rule.

For the CCR calculation process, we used the same general approach that we used in developing the final APC rates for CY 2007 and thereafter, using the revised CCR calculation that excluded the costs of paramedical education programs and weighted the outpatient charges by the volume of outpatient services furnished by the hospital. We refer readers to the CY 2007 OPPS/ASC final rule with comment period for more information (71 FR 67983 through 67985). We first limited the population of cost reports to only those hospitals that filed outpatient claims in CY 2013 before determining whether the CCRs for such hospitals were valid.

We then calculated the CCRs for each cost center and the overall ancillary CCR for each hospital for which we had claims data. We did this using hospital-specific data from the Hospital Cost Report Information System (HCRIS). We used the most recent available cost report data, which, in most cases, were from cost reports with cost reporting periods beginning in CY 2012. For this proposed rule, we used the most recently submitted cost reports to calculate the CCRs to be used to calculate costs for the proposed CY 2015 OPPS payment rates. If the most recently available cost report was submitted but not settled, we looked at the last settled cost report to determine the ratio of submitted to settled cost using the overall ancillary CCR, and we then adjusted the most recent available submitted, but not settled, cost report using that ratio. We then calculated both an overall ancillary CCR and cost center-specific CCRs for each hospital. We used the overall ancillary CCR referenced above for all purposes that require use of an overall ancillary CCR. We are proposing to continue this longstanding methodology for the calculation of costs for CY 2015.

Since the implementation of the OPPS, some commenters have raised concerns about potential bias in the OPPS cost-based weights due to ''charge compression,'' which is the practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services. As a result, the cost-based weights may reflect some aggregation bias, undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR, is applied to items of widely varying costs in the same cost center. This issue was evaluated in a report by the Research Triangle Institute, International (RTI). The RTI final report can be found on RTI's Web site at: *http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_ratios_200807_Final.pdf*. For a complete discussion of the RTI recommendations, public comments, and our responses, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527).

We addressed the RTI finding that there was aggregation bias in both the IPPS and the OPPS cost estimation of expensive and inexpensive medical supplies in the FY 2009 IPPS final rule (73 FR 48458 through 45467). Specifically, we created one cost center for ''Medical Supplies Charged to Patients'' and one cost center for ''Implantable Devices Charged to Patients,'' essentially splitting the then current cost center for ''Medical Supplies Charged to Patients'' into one cost center for low-cost medical supplies and another cost center for high-cost implantable devices in order to mitigate some of the effects of charge compression. In determining the items that should be reported in these respective cost centers, we adopted commenters' recommendations that hospitals should use revenue codes established by the AHA's NUBC to determine the items that should be reported in the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers. For a complete discussion of the rationale for the creation of the new cost center for ''Implantable Devices Charged to

Patients,'' a summary of public comments received, and our responses to those public comments, we refer readers to the FY 2009 IPPS final rule.

The cost center for ''Implantable Devices Charged to Patients'' has been available for use for cost reporting periods beginning on or after May 1, 2009. In the CY 2013 OPPS/ASC final rule with comment period, we determined that a significant volume of hospitals were utilizing the ''Implantable Devices Charged to Patients'' cost center. Because a sufficient amount of data from which to generate a meaningful analysis was available, we established in the CY 2013 OPPS/ASC final rule with comment period a policy to create a distinct CCR using the ''Implantable Devices Charged to Patients'' cost center (77 FR 68225). We retained this policy for the CY 2014 OPPS and are proposing to continue this practice for the CY 2015 OPPS.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create new standard cost centers for ''Computed Tomography (CT),'' ''Magnetic Resonance Imaging (MRI),'' and ''Cardiac Catheterization,'' and to require that hospitals report the costs and charges for these services under these new cost centers on the revised Medicare cost report Form CMS 2552–10. As we discussed in the FY 2009 IPPS and CY 2009 OPPS/ASC proposed and final rules, RTI also found that the costs and charges of CT scans, MRIs, and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI concluded that both the IPPS and the OPPS relative payment weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRIs, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the cost from charges on claims data. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a more detailed discussion on the reasons for the creation of standard cost centers for CT scans, MRIs, and cardiac catheterization. The new standard cost centers for CT scans, MRIs, and cardiac catheterization were effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10.

Using the December 2013 HCRIS update which we used to estimate costs in the CY 2015 OPPS ratesetting process, we were able to calculate a valid implantable device CCR for 2,895 hospitals, a valid MRI CCR for 1,886 hospitals, a valid CT scan CCR for 1,976 hospitals, and a valid Cardiac Catheterization CCR for 1,364 hospitals.

In our CY 2014 OPPS/ASC proposed rule discussion (78 FR 43549), we noted that, for CY 2014, the estimated changes in geometric mean estimated APC cost of using data from the new standard cost centers for CT scans and MRIs appeared consistent with RTI's analysis of cost report and claims data in the July 2008 final report (pages 5 and 6). RTI concluded that ''in hospitals that aggregate data for CT scanning, MRI, or nuclear medicine services with the standard line for Diagnostic Radiology, costs for these services all appear substantially overstated, while the costs for plain films, ultrasound and other imaging procedures are correspondingly understated.'' We also noted that there were limited additional impacts in the implantable device-related APCs from adopting the new cost report Form CMS 2552–10 because we had used data from the standard cost center for implantable medical devices beginning in CY 2013 OPPS ratesetting, as discussed above.

As we indicated in prior rulemaking (77 FR 68223 through 68225), once we determined that cost report data for the new standard cost centers were sufficiently available, we would analyze that data and, if appropriate, we would propose to use the distinct CCRs for new standard cost centers described above in the calculation of the OPPS relative payment weights. As stated in the CY 2014 OPPS/ASC proposed rule (78 FR 43550), we have conducted our analysis and concluded that we should develop distinct CCRs for each of the new cost centers and use them in ratesetting. Therefore, we began in the CY 2014 OPPS, and are proposing to continue for the CY 2015 OPPS, to calculate the OPPS relative payment weights using distinct CCRs for cardiac catheterization, CT scan, MRI, and implantable medical devices. Section XXIII. of this proposed rule includes the impacts of calculating the proposed CY 2015 OPPS relative payment weights using these new standard cost centers.

TABLE 2—CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost allocation method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0480	0.0620	0.0918	0.1164
Square Feet Only	0.0383	0.0503	0.0793	0.1036
Direct Assign	0.0683	0.0761	0.1069	0.1312
Dollar Value	0.0584	0.0739	0.1055	0.1299
Direct Assign and Dollar Value	0.0584	0.0738	0.1053	0.1294

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847), we finalized a policy to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs associated with the CT and MRI APCs. This change allows hospitals additional time to use one of the more accurate cost allocation methods, and thereby improve the accuracy of the CCRs on which the OPPS relative payment weights are developed. As part of this transitional policy to estimate the CT and MRI APC relative payment weights using only cost data from providers that do not use ''square feet'' as the cost allocation statistic, we stated in the CY 2014 OPPS/ASC final rule with comment period that we will sunset this policy in 4 years once the updated cost report data become available for ratesetting purposes. We stated that we believe that 4 years is sufficient time for hospitals that have not done so to transition to a more accurate cost allocation method and for the related data to be available for ratesetting purposes. Therefore, in CY 2018, we will estimate the CT and MRI APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic employed.

TABLE 3—PERCENTAGE CHANGE IN ESTIMATED COST FOR CT AND MRI APCS WHEN EXCLUDING CLAIMS FROM PROVIDERS USING ''SQUARE FEET'' AS THE COST ALLOCATION METHOD

Proposed CY 2015 APC	Proposed CY 2015 APC descriptor	Percent change
0283	Computed Tomography with Contrast	9.3
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	4.2
0331	Combined Abdomen and Pelvis CT without Contrast	12.0
0332	Computed Tomography without Contrast	14.1
0333	Computed Tomography without Contrast followed by Contrast	12.1
0334	Combined Abdomen and Pelvis CT with Contrast	10.1
0336	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	7.4
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast f	6.0
0383	Cardiac Computed Tomographic Imaging	4.3
0662	CT Angiography	10.3
8005	CT and CTA without Contrast Composite	12.7
8006	CT and CTA with Contrast Composite	9.2
8007	MRI and MRA without Contrast Composite	6.3
8008	MRI and MRA with Contrast Composite	6.3

In summary, we are proposing to continue using data from the ''Implantable Devices Charged to Patients'' and ''Cardiac Catheterization'' cost centers to create distinct CCRs for use in calculating the OPPS relative payment weights for the CY 2015 OPPS. For the ''Magnetic Resonance Imaging (MRI)'' and ''Computed Tomography (CT) Scan'' APCs identified in Table 3 of this proposed rule, we are proposing to continue our policy of removing claims from cost modeling for those providers using ''square feet'' as the cost allocation statistic for the CY 2015 OPPS.

2. Proposed Data Development Process and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the proposed OPPS payment rates for CY 2015. The Hospital OPPS page on the CMS Web site on which this proposed rule is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available for purchase under a CMS data use agreement. The CMS Web site, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about purchasing the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–9–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2013 claims that were used to calculate the proposed payment rates for the CY 2015 OPPS.

In the history of the OPPS, we have traditionally established the scaled relative weights on which payments are based using APC median costs, which is a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For CY 2015, we are proposing to continue to use geometric mean costs to calculate the relative weights on which the proposed CY 2015 OPPS payments rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.f. of this proposed rule to calculate the costs we used to establish the proposed relative weights used in calculating the proposed OPPS payment rates for CY 2015 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

a. Claims Preparation

For this proposed rule, we used the CY 2013 hospital outpatient claims processed through December 31, 2013, to calculate the geometric mean costs of APCs that underpin the proposed relative payment weights for CY 2015. To begin the calculation of the proposed relative payment weights for CY 2015, we pulled all claims for outpatient services furnished in CY 2013 from the national claims history file. This is not the population of claims paid under the OPPS, but all outpatient claims (including, for example, critical access hospital (CAH) claims and hospital claims for clinical laboratory tests for persons who are neither inpatients nor outpatients of the hospital).

We then excluded claims with condition codes 04, 20, 21, and 77 because these are claims that providers submitted to Medicare knowing that no payment would be made. For example, providers submit claims with a condition code 21 to elicit an official denial notice from Medicare and document that a service is not covered. We then excluded claims for services furnished in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands because hospitals in those geographic areas are not paid under the OPPS, and, therefore, we do not use claims for services furnished in these areas in ratesetting.

We divided the remaining claims into the three groups shown below. Groups 2 and 3 comprise the 119 million claims that contain hospital bill types paid under the OPPS.

1. Claims that were not bill types 12X (Hospital Inpatient (Medicare Part B only)), 13X (Hospital Outpatient), 14X (Hospital—Laboratory Services Provided to Nonpatients), or 76X (Clinic—Community Mental Health Center). Other bill types are not paid under the OPPS; therefore, these claims were not used to set OPPS payment.

2. Claims that were bill types 12X, 13X or 14X. Claims with bill types 12X

and 13X are hospital outpatient claims. Claims with bill type 14X are laboratory specimen claims.

3. Claims that were bill type 76X (CMHC).

To convert charges on the claims to estimated cost, we multiplied the charges on each claim by the appropriate hospital-specific CCR associated with the revenue code for the charge as discussed in section II.A.1.c. of this proposed rule. We then flagged and excluded CAH claims (which are not paid under the OPPS) and claims from hospitals with invalid CCRs. The latter included claims from hospitals without a CCR; those from hospitals paid an all-inclusive rate; those from hospitals with obviously erroneous CCRs (greater than 90 or less than 0.0001); and those from hospitals with overall ancillary CCRs that were identified as outliers (that exceeded +/− 3 standard deviations from the geometric mean after removing error CCRs). In addition, we trimmed the CCRs at the cost center (that is, departmental) level by removing the CCRs for each cost center as outliers if they exceeded +/- 3 standard deviations from the geometric mean. We used a four-tiered hierarchy of cost center CCRs, which is the revenue code-to-cost center crosswalk, to match a cost center to every possible revenue code appearing in the outpatient claims that is relevant to OPPS services, with the top tier being the most common cost center and the last tier being the default CCR. If a hospital's cost center CCR was deleted by trimming, we set the CCR for that cost center to ''missing'' so that another cost center CCR in the revenue center hierarchy could apply. If no other cost center CCR could apply to the revenue code on the claim, we used the hospital's overall ancillary CCR for the revenue code in question as the default CCR. For example, if a visit was reported under the clinic revenue code but the hospital did not have a clinic cost center, we mapped the hospital-specific overall ancillary CCR to the clinic revenue code. The revenue code-to-cost center crosswalk is available for inspection on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Revenue codes that we do not use in establishing relative costs or to model impacts are identified with an ''N'' in the revenue code-to-cost center crosswalk.

We applied the CCRs as described above to claims with bill type 12X, 13X, or 14X, excluding all claims from CAHs and hospitals in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands and claims from all hospitals for which CCRs were flagged as invalid.

We identified claims with condition code 41 as partial hospitalization services of hospitals and moved them to another file. We note that the separate file containing partial hospitalization claims is included in the files that are available for purchase as discussed above.

We then excluded claims without a HCPCS code. We moved to another file claims that contained only influenza and pneumococcal pneumonia (PPV) vaccines. Influenza and PPV vaccines are paid at reasonable cost; therefore, these claims are not used to set OPPS rates.

We next copied line-item costs for drugs, blood, and brachytherapy sources to a separate file (the lines stay on the claim, but are copied onto another file). No claims were deleted when we copied these lines onto another file. These line-items are used to calculate a per unit arithmetic and geometric mean and median cost and a per day arithmetic and geometric mean and median cost for drugs and nonimplantable biologicals, therapeutic radiopharmaceutical agents, and brachytherapy sources, as well as other information used to set payment rates, such as a unit-to-day ratio for drugs.

Prior to CY 2013, our payment policy for nonpass-through separately paid drugs and biologicals was based on a redistribution methodology that accounted for pharmacy overhead by allocating cost from packaged drugs to separately paid drugs. This methodology typically would have required us to reduce the cost associated with packaged coded and uncoded drugs in order to allocate that cost. However, for CY 2013, we paid for separately payable drugs and biologicals under the OPPS at ASP+6 percent, based upon the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. Under that policy, we did not redistribute the pharmacy overhead costs from packaged drugs to separately paid drugs. For the CY 2014 OPPS, we continued the CY 2013 payment policy for separately payable drugs and biologicals, and we are proposing to continue this payment policy for CY 2015. We refer readers to section V.B.3. of this proposed rule for a complete discussion of our CY 2015 proposed payment policy for separately paid drugs and biologicals.

We then removed line-items that were not paid during claim processing, presumably for a line-item rejection or denial. The number of edits for valid OPPS payment in the Integrated Outpatient Code Editor (I/OCE) and elsewhere has grown significantly in the past few years, especially with the implementation of the full spectrum of National Correct Coding Initiative (NCCI) edits. To ensure that we are using valid claims that represent the cost of payable services to set payment rates, we removed line-items with an OPPS status indicator that were not paid during claims processing in the claim year, but have a status indicator of ''S,'' ''T,'' and ''V'' in the prospective year's payment system. This logic preserves charges for services that would not have been paid in the claim year but for which some estimate of cost is needed for the prospective year, such as services newly removed from the inpatient list for CY 2014 that were assigned status indicator ''C'' in the claim year. It also preserves charges for packaged services so that the costs can be included in the cost of the services with which they are reported, even if the CPT codes for the packaged services were not paid because the service is part of another service that was reported on the same claim or the code otherwise violates claims processing edits.

For CY 2015, we are proposing to continue the policy we implemented for CY 2013 and CY 2014 to exclude line-item data for pass-through drugs and biologicals (status indicator ''G'' for CY 2013) and nonpass-through drugs and biologicals (status indicator ''K'' for CY 2013) where the charges reported on the claim for the line were either denied or rejected during claims processing. Removing lines that were eligible for payment but were not paid ensures that we are using appropriate data. The trim avoids using cost data on lines that we believe were defective or invalid because those rejected or denied lines did not meet the Medicare requirements for payment. For example, edits may reject a line for a separately paid drug because the number of units billed exceeded the number of units that would be reasonable and, therefore, is likely a billing error (for example, a line reporting 55 units of a drug for which 5 units is known to be a fatal dose). As with our trimming in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74849) of line-items with a status indicator of ''S,'' ''T,'' ''V,'' or ''X,'' we believe that unpaid line-items represent services that are invalidly reported and, therefore, should not be used for ratesetting. We believe that removing lines with valid status indicators that were edited and not paid during claims processing increases the accuracy of the data used for ratesetting purposes.

For the CY 2015 OPPS, as part of our proposal to continue packaging clinical diagnostic laboratory tests, we also are proposing to apply the line item trim to these services if they did not receive payment in the claims year. Removing these lines ensures that, in establishing the CY 2015 OPPS relative payments weights, we appropriately allocate the costs associated with packaging these services.

b. Splitting Claims and Creation of ''Pseudo'' Single Procedure Claims

(1) Splitting Claims

For the CY 2015 OPPS, we then split the remaining claims into five groups: single majors; multiple majors; single minors; multiple minors; and other claims. (Specific definitions of these groups are presented below.) We note that, under the proposed CY 2015 OPPS packaging policy, we are proposing to delete status indicator ''X'' and revise the title and description of status indicator ''Q1'' to reflect that deletion, as discussed in sections II.A.3. and XI. of this proposed rule. We note that we also are proposing to create status indicator ''J1'' to reflect the comprehensive APCs discussed in section II.A.2.e. of this proposed rule. For CY 2015, we are proposing to define major procedures as any HCPCS code having a status indicator of ''J1,'' ''S,'' ''T,'' or ''V''; define minor procedures as any code having a status indicator of ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N''; and classify ''other'' procedures as any code having a status indicator other than one that we have classified as major or minor. For CY 2015, we are proposing to continue to assign status indicator ''R'' to blood and blood products; status indicator ''U'' to brachytherapy sources; status indicator ''Q1'' to all ''STV-packaged codes''; status indicator ''Q2'' to all ''T-packaged codes''; and status indicator ''Q3'' to all codes that may be paid through a composite APC based on composite-specific criteria or paid separately through single code APCs when the criteria are not met.

As discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68709), we established status indicators ''Q1,'' ''Q2,'' and ''Q3'' to facilitate identification of the different categories of codes. We are proposing to treat these codes in the same manner for data purposes for CY 2015 as we have treated them since CY 2008. Specifically, we are continuing to evaluate whether the criteria for separate payment of codes with status indicator ''Q1'' or ''Q2'' are met in determining whether they are treated as major or minor codes. Codes with status indicator ''Q1'' or ''Q2'' are carried through the data either with status indicator ''N'' as packaged or, if they meet the criteria for separate payment, they are given the status indicator of the APC to which they are assigned and are considered as ''pseudo'' single procedure claims for major codes. Codes assigned status indicator ''Q3'' are paid under individual APCs unless they occur in the combinations that qualify for payment as composite APCs and, therefore, they carry the status indicator of the individual APC to which they are assigned through the data process and are treated as major codes during both the split and ''pseudo'' single creation process. The calculation of the geometric mean costs for composite APCs from multiple procedure major claims is discussed in section II.A.2.f. of this proposed rule.

Specifically, we are proposing to divide the remaining claims into the following five groups:

1. *Single Procedure Major Claims:* Claims with a single separately payable procedure (that is, status indicator ''S,'' ''T,'' or ''V'' which includes codes with status indicator ''Q3''); claims with status indicator ''J1,'' which receive special processing for comprehensive APCs, as discussed in section II.A.2.e. of this proposed rule; claims with one unit of a status indicator ''Q1'' code (''STV-packaged'') where there was no code with status indicator ''S,'' ''T,'' or ''V'' on the same claim on the same date; or claims with one unit of a status indicator ''Q2'' code (''T-packaged'') where there was no code with a status indicator ''T'' on the same claim on the same date.

2. *Multiple Procedure Major Claims:* Claims with more than one separately payable procedure (that is, status indicator ''S,'' ''T,'' or ''V'' which includes codes with status indicator ''Q3''), or multiple units of one payable procedure. These claims include those codes with a status indicator ''Q2'' code (''T-packaged'') where there was no procedure with a status indicator ''T'' on the same claim on the same date of service but where there was another separately paid procedure on the same claim with the same date of service (that is, another code with status indicator ''S'' or ''V''). We also include in this set claims that contained one unit of one code when the bilateral modifier was appended to the code and the code was conditionally or independently bilateral. In these cases, the claims represented more than one unit of the service described by the code, notwithstanding that only one unit was billed.

3. *Single Procedure Minor Claims:* Claims with a single HCPCS code that was assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N'' and not status indicator ''Q1'' (''STV-packaged'') or status indicator ''Q2'' (''T-packaged'') code.

4. *Multiple Procedure Minor Claims:* Claims with multiple HCPCS codes that are assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N''; claims that contain more than one code with status indicator ''Q1'' (''STV-packaged'') or more than one unit of a code with status indicator ''Q1'' but no codes with status indicator ''S,'' ''T,'' or ''V'' on the same date of service; or claims that contain more than one code with status indicator ''Q2'' (T-packaged), or ''Q2'' and ''Q1,'' or more than one unit of a code with status indicator ''Q2'' but no code with status indicator ''T'' on the same date of service.

5. *Non-OPPS Claims:* Claims that contain no services payable under the OPPS (that is, all status indicators other than those listed for major or minor status). These claims were excluded from the files used for the OPPS. Non-OPPS claims have codes paid under other fee schedules, for example, durable medical equipment, and do not contain a code for a separately payable or packaged OPPS service. Non-OPPS claims include claims for therapy services paid sometimes under the OPPS but billed, in these non-OPPS cases, with revenue codes indicating that the therapy services would be paid under the Medicare Physician Fee Schedule (MPFS).

The claims listed in numbers 1, 2, 3, and 4 above are included in the data file that can be purchased as described above. Claims that contain codes to which we have assigned status indicators ''Q1'' (''STV-packaged'') and ''Q2'' (''T-packaged'') appear in the data for the single major file, the multiple major file, and the multiple minor file used for ratesetting. Claims that contain codes to which we have assigned status indicator ''Q3'' (composite APC members) appear in both the data of the single and multiple major files used in this proposed rule, depending on the specific composite calculation.

(2) Creation of ''Pseudo'' Single Procedure Claims

To develop ''pseudo'' single procedure claims for this proposed rule, we examined both the multiple procedure major claims and the multiple procedure minor claims. We first examined the multiple major procedure claims for dates of service to determine if we could break them into ''pseudo'' single procedure claims using

the dates of service for all lines on the claim. If we could create claims with single major procedures by using dates of service, we created a single procedure claim record for each separately payable procedure on a different date of service (that is, a ''pseudo'' single procedure claim).

We also are proposing to use the bypass codes listed in Addendum N to this proposed rule (which is available via the Internet on our Web site) and discussed in section II.A.1.b. of this proposed rule to remove separately payable procedures which we determined contained limited or no packaged costs or that were otherwise suitable for inclusion on the bypass list from a multiple procedure bill. As discussed above, we ignore the ''overlap bypass codes,'' that is, those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs, in this initial assessment for ''pseudo'' single procedure claims. The proposed CY 2015 ''overlap bypass codes'' are listed in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site). When one of the two separately payable procedures on a multiple procedure claim was on the bypass list, we split the claim into two ''pseudo'' single procedure claim records. The single procedure claim record that contained the bypass code did not retain packaged services. The single procedure claim record that contained the other separately payable procedure (but no bypass code) retained the packaged revenue code charges and the packaged HCPCS code charges. We also removed lines that contained multiple units of codes on the bypass list and treated them as ''pseudo'' single procedure claims by dividing the cost for the multiple units by the number of units on the line. If one unit of a single, separately payable procedure code remained on the claim after removal of the multiple units of the bypass code, we created a ''pseudo'' single procedure claim from that residual claim record, which retained the costs of packaged revenue codes and packaged HCPCS codes. This enabled us to use claims that would otherwise be multiple procedure claims and could not be used.

We then assessed the claims to determine if the proposed criteria for the multiple imaging composite APCs, discussed in section II.A.2.f.(5) of this proposed rule, were met. If the criteria for the imaging composite APCs were met, we created a ''single session'' claim for the applicable imaging composite service and determined whether we could use the claim in ratesetting. For HCPCS codes that are both conditionally packaged and are members of a multiple imaging composite APC, we first assessed whether the code would be packaged and, if so, the code ceased to be available for further assessment as part of the composite APC. Because the packaged code would not be a separately payable procedure, we considered it to be unavailable for use in setting the composite APC costs on which the proposed CY 2015 OPPS relative payment weights are based. Having identified ''single session'' claims for the imaging composite APCs, we reassessed the claim to determine if, after removal of all lines for bypass codes, including the ''overlap bypass codes,'' a single unit of a single separately payable code remained on the claim. If so, we attributed the packaged costs on the claim to the single unit of the single remaining separately payable code other than the bypass code to create a ''pseudo'' single procedure claim. We also identified line-items of overlap bypass codes as a ''pseudo'' single procedure claim. This allowed us to use more claims data for ratesetting purposes.

We also are proposing to examine the multiple procedure minor claims to determine whether we could create ''pseudo'' single procedure claims. Specifically, where the claim contained multiple codes with status indicator ''Q1'' (''STV-packaged'') on the same date of service or contained multiple units of a single code with status indicator ''Q1,'' we selected the status indicator ''Q1'' HCPCS code that had the highest CY 2014 relative payment weight, and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q1.'' We then packaged all costs for the following into a single cost for the ''Q1'' HCPCS code that had the highest CY 2014 relative payment weight to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q1'' HCPCS code with the highest CY 2014 relative payment weight; other codes with status indicator ''Q1''; and all other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from the data status indicator of ''N'' to the status indicator of the APC to which the selected procedure was assigned for further data processing and considered this claim as a major procedure claim. We used this claim in the calculation of the APC geometric mean cost for the status indicator ''Q1'' HCPCS code.

Similarly, if a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') or multiple units of a single code with status indicator ''Q2,'' we selected the status indicator ''Q2'' HCPCS code that had the highest CY 2014 relative payment weight and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the ''Q2'' HCPCS code that had the highest CY 2014 relative payment weight to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2014 relative payment weight; other codes with status indicator ''Q2''; and other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned, and we considered this claim as a major procedure claim.

If a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') and status indicator ''Q1'' (''STV-packaged''), we selected the T-packaged status indicator ''Q2'' HCPCS code that had the highest relative payment weight for CY 2014 and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the selected (''T-packaged'') HCPCS code to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2014 relative payment weight; other codes with status indicator ''Q2''; codes with status indicator ''Q1'' (''STV-packaged''); and other packaged HCPCS codes and packaged revenue code costs. We selected status indicator ''Q2'' HCPCS codes instead of ''Q1'' HCPCS codes because ''Q2'' HCPCS codes have higher CY 2014 relative payment weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2014 relative payment weight, it became the primary code for the simulated single bill process. We changed the status indicator for the selected status indicator ''Q2'' (''T-packaged'') code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned and we considered this claim as a major procedure claim.

We then applied our proposed process for creating ''pseudo'' single procedure claims to the conditionally packaged codes that do not meet the

criteria for packaging, which enabled us to create single procedure claims from them, if they met the criteria for single procedure claims. Conditionally packaged codes are identified using status indicators ''Q1'' and ''Q2,'' and are described in section XI.A. of this proposed rule.

Lastly, we excluded those claims that we were not able to convert to single procedure claims even after applying all of the techniques for creation of ''pseudo'' single procedure claims to multiple procedure major claims and to multiple procedure minor claims. As has been our practice in recent years, we also excluded claims that contained codes that were viewed as independently or conditionally bilateral and that contained the bilateral modifier (Modifier 50 (Bilateral procedure)) because the line-item cost for the code represented the cost of two units of the procedure, notwithstanding that hospitals billed the code with a unit of one.

We are proposing to continue to apply the methodology described above for the purpose of creating ''pseudo'' single procedure claims for the CY 2015 OPPS.

c. Completion of Claim Records and Geometric Mean Cost Calculations

(1) General Process

We then packaged the costs of packaged HCPCS codes (codes with status indicator ''N'' listed in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and the costs of those lines for codes with status indicator ''Q1'' or ''Q2'' when they are not separately paid), and the costs of the services reported under packaged revenue codes in Table 4 below that appeared on the claim without a HCPCS code into the cost of the single major procedure remaining on the claim. For a more complete discussion of our proposed CY 2015 OPPS packaging policy, we refer readers to section II.A.3. of this proposed rule.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66606), for the CY 2008 OPPS, we adopted an APC Panel recommendation that CMS should review the final list of packaged revenue codes for consistency with OPPS policy and ensure that future versions of the I/OCE edit accordingly. As we have in the past, we are proposing to continue to compare the final list of packaged revenue codes that we adopt for CY 2015 to the revenue codes that the I/OCE will package for CY 2015 to ensure consistency.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68531), we replaced the NUBC standard abbreviations for the revenue codes listed in Table 2 of the CY 2009 OPPS/ASC proposed rule with the most current NUBC descriptions of the revenue code categories and subcategories to better articulate the meanings of the revenue codes without changing the list of revenue codes. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60362 through 60363), we finalized changes to the packaged revenue code list based on our examination of the updated NUBC codes and public comment on the CY 2010 proposed list of packaged revenue codes.

For CY 2015, as we did for CY 2014, we reviewed the changes to revenue codes that were effective during CY 2013 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we would propose to package for CY 2015. We believe that the charges reported under the revenue codes listed in Table 4 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2015, we are proposing to continue to package the costs that we derive from the charges reported without HCPCS codes under the revenue codes displayed in Table 4 below for purposes of calculating the geometric mean costs on which the proposed CY 2015 OPPS/ASC payment rates are based.

TABLE 4—PROPOSED CY 2015 PACKAGED REVENUE CODES

Revenue code	Description
0250	Pharmacy; General Classification.
0251	Pharmacy; Generic Drugs.
0252	Pharmacy; Non-Generic Drugs.
0254	Pharmacy; Drugs Incident to Other Diagnostic Services.
0255	Pharmacy; Drugs Incident to Radiology.
0257	Pharmacy; Non-Prescription.
0258	Pharmacy; IV Solutions.
0259	Pharmacy; Other Pharmacy.
0260	IV Therapy; General Classification.
0261	IV Therapy; Infusion Pump.
0262	IV Therapy; IV Therapy/Pharmacy Svcs.
0263	IV Therapy; IV Therapy/Drug/Supply Delivery.
0264	IV Therapy; IV Therapy/Supplies.
0269	IV Therapy; Other IV Therapy.
0270	Medical/Surgical Supplies and Devices; General Classification.
0271	Medical/Surgical Supplies and Devices; Non-sterile Supply.
0272	Medical/Surgical Supplies and Devices; Sterile Supply.
0275	Medical/Surgical Supplies and Devices; Pacemaker.
0276	Medical/Surgical Supplies and Devices; Intraocular Lens.
0278	Medical/Surgical Supplies and Devices; Other Implants.
0279	Medical/Surgical Supplies and Devices; Other.Supplies/Devices.
0280	Oncology; General Classification.
0289	Oncology; Other Oncology.
0343	Nuclear Medicine; Diagnostic Radiopharmaceuticals.
0344	Nuclear Medicine; Therapeutic Radiopharmaceuticals.
0370	Anesthesia; General Classification.
0371	Anesthesia; Anesthesia Incident to Radiology.
0372	Anesthesia; Anesthesia Incident to Other DX Services.
0379	Anesthesia; Other Anesthesia.
0390	Administration, Processing and Storage for Blood and Blood Components; General Classification.
0392	Administration, Processing and Storage for Blood and Blood Components; Processing and Storage.

TABLE 4—PROPOSED CY 2015 PACKAGED REVENUE CODES—Continued

Revenue code	Description
0399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling.
0621	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Radiology.
0622	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Other DX Services.
0623	Medical Supplies—Extension of 027X, Surgical Dressings.
0624	Medical Surgical Supplies—Extension of 027X; FDA Investigational Devices.
0630	Pharmacy—Extension of 025X; Reserved.
0631	Pharmacy—Extension of 025X; Single Source Drug.
0632	Pharmacy—Extension of 025X; Multiple Source Drug
0633	Pharmacy—Extension of 025X; Restrictive Prescription
0681	Trauma Response; Level I Trauma.
0682	Trauma Response; Level II Trauma.
0683	Trauma Response; Level III Trauma.
0684	Trauma Response; Level IV Trauma.
0689	Trauma Response; Other.
0700	Cast Room; General Classification.
0710	Recovery Room; General Classification.
0720	Labor Room/Delivery; General Classification.
0721	Labor Room/Delivery; Labor.
0732	EKG/ECG (Electrocardiogram); Telemetry.
0762	Specialty services; Observation Hours.
0801	Inpatient Renal Dialysis; Inpatient Hemodialysis.
0802	Inpatient Renal Dialysis; Inpatient Peritoneal Dialysis (Non-CAPD).
0803	Inpatient Renal Dialysis; Inpatient Continuous Ambulatory Peritoneal Dialysis (CAPD).
0804	Inpatient Renal Dialysis; Inpatient Continuous Cycling Peritoneal Dialysis (CCPD).
0809	Inpatient Renal Dialysis; Other Inpatient Dialysis.
0810	Acquisition of Body Components; General Classification.
0819	Acquisition of Body Components; Other Donor.
0821	Hemodialysis—Outpatient or Home; Hemodialysis Composite or Other Rate.
0824	Hemodialysis—Outpatient or Home; Maintenance—100%.
0825	Hemodialysis—Outpatient or Home; Support Services.
0829	Hemodialysis—Outpatient or Home; Other OP Hemodialysis.
0942	Other Therapeutic Services (also see 095X, an extension of 094x); Education/Training.
0943	Other Therapeutic Services (also see 095X, an extension of 094X), Cardiac Rehabilitation.
0948	Other Therapeutic Services (also see 095X, an extension of 094X), Pulmonary Rehabilitation.

In accordance with our longstanding policy, we are proposing to continue to exclude: (1) Claims that had zero costs after summing all costs on the claim; and (2) claims containing packaging flag number 3. Effective for services furnished after July 1, 2014, the I/OCE assigned packaging flag number 3 to claims on which hospitals submitted token charges less than $1.01 for a service with status indicator ''S'' or ''T'' (a major separately payable service under the OPPS) for which the Medicare Administrative Contractor (MAC) was required to allocate the sum of charges for services with a status indicator equaling ''S'' or ''T'' based on the relative payment weight of the APC to which each code was assigned. We do not believe that these charges, which were token charges as submitted by the hospital, are valid reflections of hospital resources. Therefore, we deleted these claims. We also deleted claims for which the charges equaled the revenue center payment (that is, the Medicare payment) on the assumption that, where the charge equaled the payment, to apply a CCR to the charge would not yield a valid estimate of relative provider cost. We are proposing to continue these processes for the CY 2015 OPPS.

For the remaining claims, we are proposing to then standardize 60 percent of the costs of the claim (which we have previously determined to be the labor-related portion) for geographic differences in labor input costs. We made this adjustment by determining the wage index that applied to the hospital that furnished the service and dividing the cost for the separately paid HCPCS code furnished by the hospital by that wage index. The claims accounting that we provide for the proposed and final rule contains the formula we use to standardize the total cost for the effects of the wage index. As has been our policy since the inception of the OPPS, we are proposing to use the pre-reclassified wage indices for standardization because we believe that they better reflect the true costs of items and services in the area in which the hospital is located than the post-reclassification wage indices and, therefore, would result in the most accurate unadjusted geometric mean costs. We are proposing to use these pre-reclassified wage indices for standardization using the new OMB labor market area delineations described in section II.C. of this proposed rule.

In accordance with our longstanding practice, we also are proposing to exclude single and ''pseudo'' single procedure claims for which the total cost on the claim was outside 3 standard deviations from the geometric mean of units for each HCPCS code on the bypass list (because, as discussed above, we used claims that contain multiple units of the bypass codes).

After removing claims for hospitals with error CCRs, claims without HCPCS codes, claims for immunizations not covered under the OPPS, and claims for services not paid under the OPPS, approximately 114 million claims were left. Using these approximately 114 million claims, we created approximately 94 million single and ''pseudo'' single procedure claims, of which we used approximately 94 million single bills (after trimming out approximately 1 million claims as discussed in section II.A.1.a. of this proposed rule) in the CY 2015 geometric mean cost development and ratesetting.

As discussed above, the OPPS has historically developed the relative weights on which APC payments are based using APC median costs. For the

CY 2013 OPPS and the CY 2014 OPPS, we calculated the APC relative payment weights using geometric mean costs, and we are proposing to do the same for CY 2015. Therefore, the following discussion of the 2 times rule violation and the development of the relative payment weight refers to geometric means. For more detail about the CY 2015 OPPS/ASC policy to calculate relative payment weights based on geometric means, we refer readers to section II.A.2.f. of this proposed rule.

We are proposing to use these claims to calculate the CY 2015 geometric mean costs for each separately payable HCPCS code and each APC. The comparison of HCPCS code-specific and APC geometric mean costs determines the applicability of the 2 times rule. Section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group shall not be treated as comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the same group (the 2 times rule). While we have historically applied the 2 times rule based on median costs, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68270), as part of the CY 2013 policy to develop the OPPS relative payment weights based on geometric mean costs, we also applied the 2 times rule based on geometric mean costs. For the CY 2015 OPPS, we are proposing to continue to develop the APC relative payment weights based on geometric mean costs.

We note that, for purposes of identifying significant HCPCS codes for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC geometric mean cost to be significant. This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 94 million single procedure or single session claims we use for establishing geometric mean costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC geometric mean. We note that this method of identifying significant HCPCS codes within an APC for purposes of the 2 times rule was used in prior years under the median-based cost methodology. Under our proposed CY 2015 policy to continue to base the relative payment weights on geometric mean costs, we believe that this same consideration for identifying significant HCPCS codes should apply because the principles are consistent with their use in the median-based cost methodology. Unlisted codes are not used in establishing the percent of claims contributing to the APC, nor are their costs used in the calculation of the APC geometric mean. Finally, we reviewed the geometric mean costs for the services for which we are proposing to pay separately under this proposed rule, and we reassigned HCPCS codes to different APCs where it was necessary to ensure clinical and resource homogeneity within the APCs. The APC geometric means were recalculated after we reassigned the affected HCPCS codes. Both the HCPCS code-specific geometric means and the APC geometric means were weighted to account for the inclusion of multiple units of the bypass codes in the creation of ''pseudo'' single procedure claims.

As we discuss in sections II.A.2.d., II.A.2.f., and VIII.B. of this proposed rule, in some cases, APC geometric mean costs are calculated using variations of the process outlined above. Specifically, section II.A.2.d. of this proposed rule addresses the proposed calculation of single APC criteria-based geometric mean costs. Section II.A.2.f. of this proposed rule discusses the proposed calculation of composite APC criteria-based geometric mean costs. Section VIII.B. of this proposed rule addresses the methodology for calculating the proposed geometric mean costs for partial hospitalization services.

(2) Recommendations of the Panel Regarding Data Development

At the March 2014 meeting of the Panel, we discussed the claims accounting process for the CY 2014 OPPS final rule, the final CY 2014 policy of adopting the new standard cost centers for CT, MRI, and cardiac catheterization in the new Medicare cost report Form CMS–2552–10, as well as the calculation of estimated cost for those APCs.

At the March 2014 Panel meeting, the Panel made a number of recommendations related to the data process. The Panel's data-related recommendations and our responses follow.

Recommendation: The Panel recommends that the work of the Data Subcommittee continue.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that CMS provide the Panel with a list of APCs for which costs fluctuate by more than 10 percent.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that CMS provide the Panel with data on comprehensive APCs as well as the effect of conditional packaging on visit codes.

CMS Response: We are accepting this recommendation.

d. Proposed Calculation of Single Procedure APC Criteria-Based Costs

(1) Device-Dependent APCs

Historically, device-dependent APCs are populated by HCPCS codes that usually, but not always, require that a device be implanted or used to perform the procedure. The standard methodology for calculating device-dependent APC costs utilizes claims data that generally reflect the full cost of the required device by using only the subset of single procedure claims that pass the procedure-to-device and device-to-procedure edits; do not contain token charges (less than $1.01) for devices; and, until January 1, 2014, did not contain the ''FB'' modifier signifying that the device was furnished without cost to the provider, or where a full credit was received; and do not contain the ''FC'' modifier signifying that the hospital received partial credit for the device. For a full history of how we have calculated payment rates for device-dependent APCs in previous years and a detailed discussion of how we developed the standard device-dependent APC ratesetting methodology, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66739 through 66742). Overviews of the procedure-to-device edits and device-to-procedure edits used in ratesetting for device-dependent APCs are available in the CY 2005 OPPS final rule with comment period (69 FR 65761 through 65763) and the CY 2007 OPPS/ASC final rule with comment period (71 FR 68070 through 68071).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74857 through 74859), we finalized a policy to define 29 device-dependent APCs as single complete services and to assign them to comprehensive APCs that provide all-inclusive payments for those services, but we delayed

implementation of this policy until CY 2015 (78 FR 74862). This policy is a further step toward improving the prospective nature of our payments for these services where the cost of the device is relatively high compared to the other costs that contribute to the cost of the service. Table 5 of the CY 2014 OPPS/ASC final rule with comment period provided a list of the 39 APCs recognized as device-dependent APCs and identified the 29 device-dependent APCs that are converted to comprehensive APCs. In addition, in the CY 2014 OPPS/ASC final rule with comment period we finalized a policy for the treatment of the remaining 10 device-dependent APCs that applied our standard APC ratesetting methodology to calculate the CY 2014 payment rates for these APCs, but implementation of this policy was also delayed until CY 2015.

As proposed in the CY 2014 OPPS/ASC proposed rule (78 FR 43556 through 43557), for CY 2015, we are proposing to no longer implement procedure-to-device edits and device-to-procedure edits for any APC. Under this proposed policy, which was discussed but not finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74857 through 74858), hospitals are still expected to adhere to the guidelines of correct coding and append the correct device code to the claim, when applicable. However, claims would no longer be returned to providers when specific procedure and device code pairings do not appear on a claim. As we stated in both the CY 2014 OPPS/ASC proposed rule (78 FR 43556 through 43557) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 74857 through 748598), we believe that this is appropriate because of the experience hospitals now have had in coding and reporting these claims fully and, for the more costly devices, the comprehensive APCs will reliably reflect the cost of the device if it is included anywhere on the claim. Therefore, we do not believe that the burden imposed upon hospitals to adhere to the procedure-to-device edits and device-to-procedure edits and the burden imposed upon the Medicare program to maintain those edits continued to be warranted. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

The proposed CY 2015 comprehensive APC policy consolidates and restructures the 39 current device-dependent APCs into 26 (of the total 28) comprehensive APCs, which are listed below in Table 5. The comprehensive APC policy is discussed in section II.A.2.e. of this proposed rule. As a result of the proposed CY 2015 comprehensive APC policy, device-dependent APCs would no longer exist in CY 2015 because these APCs will have all been converted to comprehensive APCs. In conjunction with the proposed termination of device-dependent APCs and as discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74857 through 74858), we are proposing to no longer use procedure-to-device edits and device-to-procedure edits for any APC because we continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate considering the experience that hospitals now have in coding and reporting these claims fully and, for the more costly devices, the comprehensive APCs will reliably reflect the cost of the device if it is included anywhere on the claim.

While we believe that device-to-procedure edits and procedure-to-device edits are no longer necessary, we are sensitive to the concerns raised by stakeholders in the past about the costs of devices being reported and captured. In light of these concerns, we are proposing to create claims processing edits that require *any* of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any 1 of the 26 proposed comprehensive APCs (of a total of 28 proposed comprehensive APCs) listed below in Table 5 is reported on the claim to ensure that device costs are captured by hospitals. We expect that hospitals would use an appropriate device code consistent with correct coding in order to ensure that device costs are always reported on the claim, so that costs are appropriately captured in claims that CMS uses for ratesetting.

Table 5 below provides a list of the 26 proposed CY 2015 comprehensive APCs, which we previously recognized as device-dependent APCs for CY 2014. This proposal would result in the term ''device-dependent APC'' no longer being employed beginning in CY 2015.

TABLE 5—PROPOSED APCS THAT WOULD REQUIRE A DEVICE CODE TO BE REPORTED ON A CLAIM WHEN A PROCEDURE ASSIGNED TO ONE OF THESE APCS IS REPORTED

APC	APC Title
0039.	Level III Neurostimulator.
0061	Level II Neurostimulator.
0083	Level I Endovascular.
0084	Level I EP.
0085	Level II EP.
0086	Level III EP.
0089	Level III Pacemaker.
0090	Level II Pacemaker.
0107	Level I ICD.
0108	Level II ICD.
0202	Level V Female Reproductive.
0227	Implantation of Drug Infusion.
0229	Level II Endovascular.
0259	Level VII ENT Procedures.
0293	Level IV Intraocular.
0318	Level IV Neurostimulator.
0319	Level III Endovascular.
0384	GI Procedures with Stents.
0385	Level I Urogenital.
0386	Level II Urogenital.
0425	Level V Musculoskeletal.
0427	Level II Tube/Catheter.
0622	Level II Vascular Access.
0648	Level IV Breast Surgery.
0652	Insertion of IP/Pl. Cath.
0655	Level IV Pacemaker.

(2) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

For CY 2015, we are proposing to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products.

Specifically, in order to address the differences in CCRs and to better reflect hospitals' costs, we are proposing to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We would apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We are proposing to calculate the costs upon which the proposed CY 2015 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific simulated blood-specific CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that this methodology in CY 2015 will result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that, as discussed in section II.A.2.e. of the CY 2014 OPPS/ASC final rule with comment period and this proposed rule, we established comprehensive APCs that will provide all-inclusive payments for certain device-dependent procedures. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these comprehensive APCs. We are proposing to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the comprehensive APCs. Because the costs of blood and blood products would be reflected in the overall costs of the comprehensive APCs (and, as a result, in the proposed payment rates of the comprehensive APCs), we are proposing not to make separate payments for blood and blood products when they appear on the same claims as services assigned to the comprehensive APCs.

We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2015 payment rates for blood and blood products (which are identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

(3) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS payment methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to cost. We believe that the OPPS prospective payment methodology, as opposed to payment based on hospitals' charges adjusted to cost, would also provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66779 through 66787), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68668 through 68670), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60533 through 60537), the CY 2011 OPPS/ASC final rule with comment period (75 FR 71978 through 71981), and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74160 through 74163) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2015, we are proposing to use the costs derived from CY 2013 claims data to set the proposed CY 2015 payment rates for brachytherapy sources, as we are proposing to use to set the proposed payment rates for most other items and services that would be paid under the CY 2015 OPPS. We based the proposed payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology proposed for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also are proposing to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We are proposing to pay for the stranded and non-stranded not otherwise specified (NOS) codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also are proposing to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Pub. L. 110–275). That policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2015 payment rates for brachytherapy sources, which are identified with status indicator ''U.'' We are inviting public comments on this proposed policy and requesting recommendations for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. Such

recommendations should be directed to the Division of Outpatient Care, Mail Stop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis through our program transmittals.

e. Establishment of Comprehensive APCs

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), effective January 1, 2015, we finalized a comprehensive payment policy that bundles or ''packages'' payment for the most costly medical device implantation procedures under the OPPS at the claim level. We defined a comprehensive APC (C–APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established comprehensive APCs as a category broadly for OPPS payment and established 29 comprehensive APCs to prospectively pay for 167 of the most costly device-dependent services beginning in CY 2015 (78 FR 74910). Under this policy, we designated each service described by a HCPCS code assigned to a comprehensive APC as the primary service and, with few exceptions, consider all other services reported on a hospital Medicare Part B claim in combination with the primary service to be related to the delivery of the primary service (78 FR 74869). In addition, under this policy, we calculate a single payment for the entire hospital stay, defined by a single claim, regardless of the date of service span. This comprehensive APC packaging policy ''packages'' payment for all items and services typically packaged under the OPPS, but also packages payment for other items and services that are not typically packaged under the OPPS, except in the context of comprehensive APC payments (78 FR 74909).

Because of the overall complexity of this new policy and our introduction of complexity adjustments in the CY 2014 OPPS/ASC final rule with comment period, we modeled the dynamics of the policy as if we were implementing it for CY 2014, but delayed the effective date until January 1, 2015, to allow additional time for analysis, opportunity for public comment, and systems preparation. In this section of this CY 2015 OPPS/ASC proposed rule, we review the policies finalized in the CY 2014 OPPS/ASC final rule with comment period for comprehensive APCs. We then outline our proposed policy for CY 2015, which includes several clarifications and proposed modifications in response to public comments received. Finally, we summarize and respond to the public comments we received in response to the comprehensive APC policy outlined in the CY 2014 OPPS/ASC final rule with comment period. In this section, we use the terms ''service'' and ''procedure'' interchangeably.

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a policy with a delayed implementation date of CY 2015, whereby we designated certain covered OPD services as ''primary services'' (identified by a new OPPS status indicator of ''J1'') assigned to comprehensive APCs. When such a primary service is reported on a hospital Medicare Part B claim, taking into account the few exceptions that are discussed below, we treat all other items and services reported on the claim as integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a comprehensive service (78 FR 74865). This results in a single prospective payment for the primary, comprehensive service based on the cost of all reported services at the claim level. We only exclude charges for services that are not payable under the OPPS, such as certain mammography and ambulance services that are never covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which must receive separate payment under section 1833(t)(2)(H) of the Act; pass-through drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; and self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act (78 FR 74865).

The ratesetting process set forth in the CY 2014 OPPS/ASC final rule with comment period for the comprehensive APC payment bundle policy is summarized as follows(78 FR 74887):

APC assignment of primary (''J1'') services. During ratesetting, single claims reporting a single procedure described by a HCPCS code assigned to status indicator ''J1'' are used to establish an APC assignment for each procedure described by that HCPCS code. The geometric mean of the total estimated costs on each claim is used to establish resource similarity for each procedure code's APC assignment and is evaluated within the context of clinical similarity, with assignment starting from the APC assignments in effect for the current payment year. Claims reporting multiple procedures described by HCPCS codes assigned to status indicator ''J1'' are identified and the procedures are then assigned to a comprehensive APC based on the primary HCPCS code that has the highest APC geometric mean cost. This ensures that multiple procedures described by HCPCS codes assigned to status indicator ''J1'' reported on claims are always paid through and assigned to the comprehensive APC that would generate the highest APC payment. If multiple procedures described by HCPCS codes assigned to status indicator ''J1'' that are reported on the same claim have the same APC geometric mean estimated cost, as would be the case when two different procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to the same APC, identification of the primary service is then based on the procedure described by the HCPCS code assigned to status indicator ''J1'' with the highest HCPCS-level geometric mean cost. When there is no claims data available upon which to establish a HCPCS-level comprehensive geometric mean cost, we model a HCPCS-level geometric mean cost for the sole purpose of appropriately assigning the primary service reported on a claim. The comprehensive APC assignment of each procedure described by HCPCS codes assigned to status indicator ''J1'' is then confirmed by verifying that the APC assignment remains appropriate when considering the clinical similarity, as well as the estimated cost of all claims reporting each procedure described by HCPCS codes assigned to status indicator ''J1,'' including simple and complex claims, with multiple device-related procedures (78 FR 74887).

Complexity adjustments and determination of final comprehensive APC groupings. We then considered reassigning complex subsets of claims for each primary service described by a HCPCS code assigned to status indicator ''J1.'' All claims reporting more than one procedure described by HCPCS codes assigned to status indicator ''J1'' are evaluated for the existence of commonly occurring combinations of procedure codes reported on claims that exhibit a materially greater comprehensive geometric mean cost relative to the geometric mean cost of the claims reporting that primary service. This indicates that the subset of procedures identified by the secondary HCPCS code

has increased resource requirements relative to less complex subsets of that procedure (78 FR 74887). The CY 2014 complexity adjustment criteria are as follows:

- The comprehensive geometric mean cost of the claims reporting the combination of procedures was more than two times the comprehensive geometric mean cost of the single major claims reporting only the primary service;
- There were more than 100 claims in the data year reporting the specific code combination;
- The number of claims reporting the specific code combination exceeded 5 percent of the volume of all claims reporting the designated primary service; and
- There would be no violation of the ''2 times'' rule within the receiving comprehensive APC (78 FR 74886).

If a combination of procedure codes reported on claims is identified that meets these requirements, that is, commonly occurring and exhibiting materially greater resource requirements, the combination of procedure codes is further evaluated to confirm clinical validity as a complex subset of the primary procedure and the combination of procedure codes is then identified as complex, and primary service claims with that combination of procedure codes are subsequently reassigned as appropriate. If a combination of procedure codes does not meet the requirement for a materially greater resource requirement or does not occur commonly, the combination of procedure codes is not considered to be complex, and primary service claims with that combination of procedure codes are not reassigned. All combinations of procedures described by HCPCS codes assigned to status indicator ''J1'' for each primary service are similarly evaluated. Once all combinations of procedures described by HCPCS codes assigned to status indicator ''J1'' have been evaluated, all claims identified for reassignment for each primary service are combined and the group is assigned to a higher level comprehensive APC within a clinical family of comprehensive APCs, that is, an APC with greater estimated resource requirements than the initially assigned comprehensive APC and with appropriate clinical homogeneity. We assessed resource variation for reassigned claims within the receiving APC using the geometric mean cost for all reassigned claims for the primary service relative to other services assigned to that APC using the 2 times rule criteria (78 FR 74887).

For new HCPCS codes and codes without data, we use the best data available to us to identify combinations of procedure codes that represent a more complex form of the primary service and warrant reassignment to a higher level APC. We will reevaluate our APC assignments and identification and APC placement of complex claims once claims data become available.

(2) Proposed CY 2015 Policy for Comprehensive APCs

(a) Proposed Methodology

After consideration of the public comments we received, which are discussed in detail below, in this section we describe our proposed payment methodology for comprehensive APCs for CY 2015. The basic steps for calculating the comprehensive APC payments remain the same as those finalized in the CY 2014 OPPS/ASC final rule with comment period, except for the complexity adjustment criteria described briefly above (78 FR 74885 through 74888). For CY 2015, we are proposing to restructure and consolidate some of the current device-dependent APCs to improve both the resource and clinical homogeneity of these APCs. In addition, instead of assigning any add-on codes to status indicator ''J1'' as finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74873 through 74883), we are proposing to package all add-on codes, but to allow certain add-on codes to qualify a procedure code combination for a complexity adjustment.

Further, we are proposing to convert all current device-dependent APCs remaining after the proposed restructuring and consolidation of some of these APCs to comprehensive APCs. We also are proposing two new comprehensive APCs, C–APC 0067 for single-session cranial stereotactic radiosurgery (SRS) and C–APC 0351 for intraocular telescope implantation. In addition, we are proposing to reassign CPT codes 77424 and 77425 that describe intraoperative radiation therapy treatment (IORT) to C–APC 0648 (Level IV Breast and Skin Surgery). We discuss in detail below our proposed new complexity adjustment criteria and our proposal to package all add-on codes, but to allow complexity adjustments for qualifying code combinations of primary codes and add-on codes currently assigned to device-intensive comprehensive APCs. The steps are as follows:

Step 1: Select primary (''J1'') services. We continue to believe that the comprehensive packaging of adjunctive services into a primary service will further improve cost validity, payment accuracy, beneficiary transparency, and hospital efficiency (78 FR 74861). As in CY 2014, for CY 2015, we are proposing that services assigned to comprehensive APCs be designated as primary services for comprehensive APCs, using new status indicator ''J1'' as listed in Addendum J and Addendum B to this proposed rule (which are available via the Internet on the CMS Web site). We also are proposing to package all add-on codes, as discussed in detail below, and that none of these add-on codes will be considered primary services assigned to status indicator ''J1.''

Treatment of add-on codes. We are proposing to assign all add-on codes status indicator ''N'' (unconditionally packaged). Therefore, under this proposal no add-on codes will be assigned to status indicator ''J1.'' However, we are proposing to evaluate a limited set of add-on codes assigned to the current device-dependent APCs, and to establish that when these add-on codes are reported in conjunction with a primary service a potential complexity adjustment under the proposed complexity adjustment criteria may be warranted (discussed further in Step 5 below).

Step 2: Definition of the payment package (comprehensive service). We are proposing the following changes to the comprehensive APCs payment packaging policy for the services that are assigned to status indicator ''J1'' or designated as primary services assigned to a comprehensive APC:

- We are proposing to restructure and consolidate the current device-dependent APCs, including some procedure code reassignments to improve clinical and resource homogeneity;
- We are proposing to package all of the add-on procedure codes, after we review and evaluate add-on codes reported in conjunction with primary ''J1'' services under the proposed complexity adjustment criteria for a potential complexity adjustment;
- We are proposing to create more comprehensive APCs, including converting all device-dependent APCs (including those that were not included in the CY 2014 policy) and to create new comprehensive APCs for single session cranial stereotactic radiosurgery and intraocular telescope implantation.

As stated in the CY 2014 OPPS/ASC final rule with comment period, we define the comprehensive APC payment packaging policy as including all covered OPD services on a hospital Medicare Part B claim reporting a primary service that is assigned to status

indicator ''J1,'' excluding services that cannot be covered OPD services or that cannot by statute be paid under the OPPS. Services packaged for payment under the comprehensive APC payment packaging policy, that is, services that are typically integral, ancillary, supportive, dependent, or adjunctive to the primary service, provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; outpatient department services that are similar to therapy and delivered either by therapists or non-therapists as part of the comprehensive service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that are provided during the comprehensive service, except excluded services that are described below (78 FR 74865). Items packaged for payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and those drugs that are usually self-administered (SADs), unless they function as packaged supplies (78 FR 74868 through 74869 and 74909). We refer readers to the Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services, Section 50.2.M, for a description of our policy on self-administered drugs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

Services excluded from the comprehensive APC payment packaging policy are as follows: SADs that are not considered supplies, because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; services excluded from the OPPS according to section 1833(t)(1)(B) of the Act including recurring therapy services, which we considered unrelated to the comprehensive service (defined as therapy services reported on a separate facility claim for recurring services), ambulance services, diagnostic and screening mammography, the annual wellness visit providing personalized prevention plan services, and pass-through drugs and devices that are paid according to section 1833(t)(6) of the Act.

We also exclude preventive services defined in 42 CFR 410.2, ''(1) [t]he specific services listed in section 1861(ww)(2) of the Act, with the explicit exclusion of electrocardiograms; (2) [t]he Initial Preventive Physical Examination (IPPE) (as specified by section 1861(ww)(1) of the Act); and (3) Annual Wellness Visit (AWV), providing Personalized Prevention Plan Services (PPPS) (as specified by section 1861(hhh)(1) of the Act).'' These preventive services are listed by their HCPCS codes in Addendum J to this proposed rule and include: annual wellness visits providing personalized prevention plan services; initial preventive physical examinations; pneumococcal, influenza, and hepatitis B vaccines and administrations; mammography screenings; pap smear screenings and pelvic examination screenings; prostate cancer screening tests; colorectal cancer screening tests; diabetes outpatient self-management training services; bone mass measurements; glaucoma screenings; medical nutrition therapy services; cardiovascular screening blood tests; diabetes screening tests; ultrasound screenings for abdominal aortic aneurysm; and additional preventive services as defined in section 1861(ddd)(1) of the Act. We defined and discussed these services in detail for hospital billing purposes in the CY 2011 OPPS/ASC final rule with comment period pursuant to coverage and payment provisions in the Affordable Care Act (75 FR 72013 through 72020).

This proposed policy is consistent with our policy to exclude preventive services from the proposed ancillary services packaging policy, will encourage the provision of preventive services, and provide maximum flexibility to beneficiaries across different sites of service in receiving preventive services. In addition, the statute does not permit assessment of beneficiary cost-sharing for most preventive services, and some receive cost-based payment (75 FR 72013 through 72020; 78 FR 74962). While any beneficiary cost-sharing attributable to preventive services, if they were packaged, would be very small in relation to the comprehensive service overall, we believe that we should exclude these services from the OPPS beneficiary copayment calculations, as discussed in section II.I. of this proposed rule. We note that one preventive service (HCPCS code G0102 (Prostate cancer screening; digital rectal examination)) is proposed for continued packaging under the OPPS in CY 2015, both broadly and in the context of comprehensive services. Currently, this HCPCS code is packaged because it is included in evaluation and management services. We note that beneficiary cost-sharing is not waived for the service described by HCPCS code G0102.

Consistent with the policy finalized in the CY 2014 OPPS/ASC final rule with comment period, we exclude brachytherapy services and pass-through drugs, biologicals and devices that are separately payable by statute (78 FR 74868, 74909). In addition, we exclude services assigned to OPPS status indicator ''F'' that are not paid under the OPPS and are instead paid on a reasonable cost basis (certain CRNA services, Hepatitis B vaccines, and corneal tissue acquisition, which is not part of a comprehensive service for CY 2015). In Addendum J to this proposed rule, we list the HCPCS codes that describe the services proposed for exclusion from the comprehensive APC payment bundling policy.

As we discussed in the CY 2014 OPPS/ASC final rule with comment period, we did not model a budget neutrality adjustment for newly included services that would otherwise be paid under non-OPPS fee schedules (for example, therapy and DMEPOS) because the policy would not be implemented until CY 2015, and the estimated costs were very low (78 FR 74901). We reflect the inclusion of the proposed new costs (which remain very low) in our annual adjustment for CY 2015 budget neutrality (we refer readers to section XXI. of this proposed rule).

TABLE 6—PROPOSED COMPREHENSIVE APC PAYMENT BUNDLING POLICY EXCLUSIONS FOR CY 2015

Ambulance services.
Brachytherapy.
Diagnostic and mammography screenings.

TABLE 6—PROPOSED COMPREHENSIVE APC PAYMENT BUNDLING POLICY EXCLUSIONS FOR CY 2015—Continued

Physical therapy, speech-language pathology and occupational therapy services—Therapy services reported on a separate facility claim for recurring services.
Pass-through drugs, biologicals and devices.
Preventive services defined in 42 CFR 410.2: • Annual wellness visits providing personalized prevention plan services. • Initial preventive physical examinations. • Pneumococcal, influenza, and hepatitis B vaccines and administrations. • Mammography Screenings. • Pap smear screenings and pelvic examination screenings. • Prostate cancer screening tests. • Colorectal cancer screening tests. • Diabetes outpatient self-management training services. • Bone mass measurements. • Glaucoma screenings. • Medical nutrition therapy services. • Cardiovascular screening blood tests. • Diabetes screening tests. • Ultrasound screenings for abdominal aortic aneurysm. • Additional preventive services (as defined in section 1861(ddd)(1) of the Act).
Self-administered drugs—Drugs that are usually self-administered and do not function as supplies in the provision of the comprehensive service.
Services assigned to OPPS status indicator ''F'' (Certain CRNA services, Hepatitis B vaccines and corneal tissue acquisition).
Services assigned to OPPS status indicator ''L'' (Influenza and pneumococcal pneumonia vaccines).
Certain Part B inpatient services—Ancillary Part B inpatient services payable under Part B when the primary ''J1'' service for the claim is not a payable Part B inpatient service (for example, exhausted Medicare Part A benefits, beneficiaries with Part B only).

Step 3: Ranking of primary services initial comprehensive APC assignments. We are proposing to continue to define each hospital Medicare Part B claim reporting a single unit of a single primary service assigned to status indicator ''J1'' (approximately 80 percent of the CY 2013 claims) as a single major procedure claim (78 FR 74871). We would sum all line item charges for services included in the comprehensive APC payment, convert the charges to costs, and calculate the ''comprehensive'' geometric mean cost of one unit of each service assigned to status indicator ''J1.'' (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a comprehensive APC, inclusive of all of the items and services in the comprehensive APC payment bundle). Charges for services that would otherwise have been separately payable subject to longstanding adjustments, including the multiple procedure reduction (for example, HCPCS codes assigned to status indicators ''A,'' ''S,'' ''T,'' or ''V'') would be added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We would apply our standard data trim, excluding claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the comprehensive APCs. We are proposing to establish a ranking of each primary service (single unit only) assigned to status indicator ''J1'' according to their comprehensive geometric mean costs. For CY 2015, we are proposing not to assign any add-on codes to status indicator ''J1'' because they are proposed to be packaged.

For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof (approximately 20 percent of CY 2013 claims), we are proposing to continue to identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the comprehensive APC to which the service designated as the primary service is assigned. If the reported ''J1'' services reported on a claim map to different comprehensive APCs, we designate the ''J1'' service assigned to the comprehensive APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same comprehensive APC, we designate the most costly service as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate comprehensive APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Step 4—Complexity adjustments and determination of final comprehensive APC groupings. We are proposing to use the proposed complexity adjustments to provide increased payment for certain comprehensive services. We are proposing to apply a complexity adjustment by promoting qualifying ''J1'' service code combinations or code combinations of a ''J1'' services and certain add-on codes (as described further below) from the originating comprehensive APC (the comprehensive APC to which the designated primary service is first assigned) to a higher paying comprehensive APC in the same clinical family of comprehensive APCs, if reassignment is clinically appropriate and the reassignment would not create a 2 times rule violation in the receiving APC (the higher paying comprehensive APC in the same clinical family of comprehensive APCs). We are proposing to implement this type of complexity adjustment when the code combination represents a complex, costly form or version of the primary

service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule, that is, the comprehensive geometric mean cost of the complex code combination exceeds the comprehensive geometric mean cost of the lowest significant HCPCS code assigned to the comprehensive APC (cost threshold).

After designating a single primary service for a claim, we are proposing to evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if they meet the complexity adjustment criteria. For new HCPCS codes, we are proposing to determine initial comprehensive APC assignments and complexity adjustments using the best data available, mapping the new HCPCS codes to predecessor codes wherever possible.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we are proposing to promote the complex version of the primary service as described by the code combination to the next higher cost comprehensive APC within the clinical family, unless the APC reassignment is not clinically appropriate, the reassignment would create a 2 times rule violation in the receiving APC, or the primary service is already assigned to the highest cost APC within the comprehensive APC clinical family. We are not proposing to create new APCs with a geometric mean cost that is higher than the highest cost comprehensive APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any code combination for services assigned to a comprehensive APC will be the highest paying comprehensive APC in the clinical family.

As discussed below, we are proposing that add-on codes reported in conjunction with a ''J1'' service would receive complexity adjustments when a qualifying add-on code is reported in conjunction with the primary service assigned to status indicator ''J1'' and satisfies the criteria described above for a complexity adjustment (≥25 claims with the code combination and no violations of the 2 times rule). Any combinations of HCPCS codes that fail to meet the proposed complexity adjustment criteria (frequency and cost thresholds) would not be identified as complex subsets of the primary procedure and would not be reassigned to a higher paying comprehensive APC within the same clinical family of comprehensive APCs. We are providing the proposed list of qualifying code combinations (including add-on codes) in Addendum J to this proposed rule (which is available via the Internet on the CMS Web site).

Complexity Test for Eligible Add-On Codes. We are proposing to package all add-on codes into the payment for the comprehensive APC. However, add-on codes that are assigned to the current device-dependent APCs listed in Table 5 of this proposed rule will be evaluated for a possible complexity adjustment when they are reported in conjunction with a designated primary service assigned to status indicator ''J1.'' We are proposing to only evaluate the add-on codes that are assigned to the current device-dependent APCs for potential complexity adjustments because we believe that, in certain cases, these procedure codes may represent services with additional medical device costs that result in significantly more complex and costly procedures. To determine which combinations of primary service codes reported in conjunction with the add-on code may qualify for a complexity adjustment for CY 2015, we are proposing to apply the proposed frequency and cost criteria discussed above (25 or more claims and no ''2 times'' rule violations), testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code. If the frequency and cost criteria for a complexity adjustment are met, and reassignment to the next higher cost APC in the clinical family is appropriate, we are proposing to make a complexity adjustment for the code combination; that is, we are proposing to reassign the primary service code reported in conjunction with the add-on code combination to a higher cost comprehensive APC within the same clinical family of comprehensive APCs. If any add-on code combination reported in conjunction with the primary service code does not qualify for a complexity adjustment, payment for these services will be packaged. We are listing the complexity adjustments proposed for add-on code combinations for CY 2015, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the Internet on the CMS Web site). One primary service code and add-on code combination (CPT code 37225 and 37233) that satisfied the frequency and cost criteria is not being proposed for a complexity adjustment because we believe that these claims are miscoded. Of the 35 qualifying claims reporting this code combination, only three claims contained the appropriate base code (CPT code 37228) for CPT add-on code 37233.

We note that, in response to public comments received, we are providing in Addendum J to this proposed rule a breakdown of cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the code combinations proposed to be reassigned under a given primary code. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the last 4 digits of the designated primary service followed by ''A'' (indicating ''adjustment''). For example, the geometric mean cost listed in Addendum J for the code combination described by CPT code 33208A assigned to C–APC 0655 includes all code combinations that are proposed to be reassigned to C–APC 0655 when CPT code 33208 is the primary code. Providing the information contained in Addendum J in this proposed rule will allow stakeholders the opportunity to better assess the impact associated with the proposed reassignment of each of the code combinations eligible for a complexity adjustment.

(b) Additional Proposed Comprehensive APCs

Several commenters to the CY 2014 OPPS/ASC proposed rule questioned why we only converted a subset of the device-dependent APCs to comprehensive APCs (78 FR 74864). We responded that while we were initially adopting a subset of the most costly device-dependent services, we may extend comprehensive payments to other procedures in future years as part of a broader packaging initiative (78 FR 74864). Upon further review for CY 2015, we believe that the entire set of the currently device-dependent APCs (after the proposed reorganization and consolidation of the current device-dependent APCs) are appropriate candidates for comprehensive APC payment because the device-dependent APCs not included in last year's

comprehensive APC payment proposal are similar to the original 29 device-dependent APCs that were proposed as comprehensive APCs in CY 2014. Similar to the original 29 device-dependent APCs for CY 2014 that were converted to C–APCs, the additional device-dependent APCs that are being proposed for conversion to C–APCs contain comprehensive services primarily intended for the implantation of costly medical devices. Therefore, we are proposing to apply the comprehensive APC payment policy to the remaining device-dependent APCs for CY 2015.

In addition, since the publication of the CY 2014 OPPS/ASC final rule with comment period, stakeholders brought several services to our attention as appropriate candidates for comprehensive APC payment. Stakeholders recommended that we create comprehensive APCs for these procedures and technologies or assign them to a previously proposed comprehensive APC. We agree with the stakeholders. Similar to the other services designated as C–APCs in CY 2014, these procedures are comprehensive single-session services with high-cost implantable devices or high-cost equipment. For CY 2015, we are proposing to convert the following existing APCs into comprehensive APCs: APC 0067 (Single Session Cranial Stereotactic Radiosurgery) and APC 0351 (Level V Intraocular Surgery)). APC 0351 only contains one procedure—0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens). We also are proposing to assign the CPT codes for IORT (CPT codes 77424 and 77425) to C–APC 0648 (Level IV Breast and Skin Surgery) because IORT is a single session comprehensive service that includes breast surgery combined with a special type of radiation therapy that is delivered inside the surgical cavity but is not technically brachytherapy. The HCPCS codes that we are proposing to assign to these APCs in CY 2015 would be assigned to status indicator ''J1.''

(c) Proposed Reconfiguration and Restructuring of the Comprehensive APCs

Based on further examination of the structure of the comprehensive APCs illustrated in the CY 2014 OPPS/ASC final rule with comment period and an evaluation of their comprehensive geometric mean costs (using the updated CY 2013 claims data), we are proposing to reorganize, combine, and restructure some of the comprehensive APCs. The purpose of this APC restructuring is to improve resource and clinical homogeneity among the services assigned to certain comprehensive APCs and to eliminate APCs for clinically similar services, but with overlapping geometric mean costs. The services we are proposing to assign to each of the comprehensive APCs for CY 2015, along with the relevant cost statistics, are provided in Addendum J to this proposed rule. Addendum J is available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Table 7 below lists the additional 28 APCs proposed under the CY 2015 comprehensive APC policy.

In summary, our proposal to reorganize, combine, and restructure some of the comprehensive APCs includes the following proposed changes:

- Endovascular clinical family (renamed Vascular Procedures, VASCX). We are proposing to combine C–APCs 0082, 0083, 0104, 0229, 0319, and 0656 illustrated for CY 2014 to form three proposed levels of comprehensive endovascular procedure APCs: C–APC 0083 (Level I Endovascular Procedures); C–APC 0229 (Level II Endovascular Procedures); and C–APC 0319 (Level IV Endovascular Procedures).
- Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices (AICDP). We are proposing to combine C–APCs 0089, 0090, 0106, 0654, 0655, and 0680 as illustrated for CY 2014 to form three proposed levels of comprehensive APCs within a broader series of APCs for pacemaker implantation and similar procedures as follows: APC 0105 (Level I Pacemaker and Similar Procedures), a non-comprehensive APC; C–APC 0090 (Level II Pacemaker and Similar Procedures); C–APC 0089 (Level III Pacemaker and Similar Procedures); and C–APC 0655 (Level IV Pacemaker and Similar Procedures).
- We are proposing to delete the clinical family for Event Monitoring, which only had one comprehensive APC (C–APC 0680 (Insertion of Patient Activated Event)) with a single CPT code 33282 as illustrated for CY 2014. We also are proposing to reassign CPT code 33282 to C–APC 0090, which contains clinically similar procedures.
- In the urogenital family, we are proposing two levels instead of three levels for Urogenital Procedures, and to reassign several codes from APC 0195 to C–APC 0202 (Level V Female Reproductive Procedures).
- We are proposing to rename the arthroplasty family of APCs to Orthopedic Surgery. We also are proposing to reassign several codes from APC 0052 to C–APC 0425, which we are proposing to rename ''Level V Musculoskeletal Procedures Except Hand and Foot.''
- We are proposing three levels of electrophysiologic procedures, using the current inactive APC ''0086'' instead of APC 0444, to have consecutive APC grouping numbers for this clinical family and renaming APC 0086 ''Level III Electrophysiologic Procedures.'' In addition, we are proposing to replace composite APC 8000 with proposed C–APC 0086 as illustrated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74870).

We also are proposing three new clinical families: Gastrointestinal Procedures (GIXXX) for gastrointestinal stents, Tube/Catheter Changes (CATHX) for insertion of various catheters, and Radiation Oncology (RADTX), which would include C–APC 0067 for single session cranial SRS.

(3) Public Comments

We received nine public comments in response to the CY 2014 OPPS/ASC final rule with comment period regarding our policy for comprehensive APCs from device manufacturers, the hospital community, and others. The commenters generally supported broader payment bundles, as long as the payment bundles are appropriately and accurately structured and provide adequate payment. Commenters expressed continued concern regarding the data provided in support of the comprehensive APC policy, the ability to replicate the methodology, and the ability of comprehensive APCs to adequately pay for complex services for patients. The comments, which were largely provided in the context of specific devices or drugs, or in regard to a specific clinical family of comprehensive APCs, are summarized below and accompanied by our responses.

Endovascular Family

Comment: Several commenters addressed the endovascular family of comprehensive APCs. The commenters expressed difficulty replicating CMS' methodology, especially complexity reassignments for procedures in this family of services that is historically component-based and include many new codes and add-on codes. The commenters requested clarification of how CMS determined comprehensive APC assignments and complexity adjustments associated with add-on codes and other procedures.

One commenter expressed concern regarding payment levels for vascular

procedures involving multiple vessels. The commenter recommended changes to the complexity adjustment criteria in order to allow for adjustments and to provide adequate payment for seven code combinations of lower extremity endovascular revascularization procedures assigned to C–APCs 0083 (Level I Endovascular Procedures), 0229 (Level II Endovascular Procedures) and 0445 (Level III Endovascular Procedures). The code combinations identified by the commenter were CPT code 37221 and 37222; 37229 and 37232; 37230 and 37232; 37231 and 37232; 37229 and 37234; 37231 and 37233; and 37231 and 37234. Procedures described by add-on codes (CPT codes 37222, 37232, 37233 and 37234) are furnished in conjunction with each of these code combinations. The commenter stated that each of the code combinations failed to meet the CY 2014 finalized cost threshold for a complexity adjustment (for example, the comprehensive geometric mean cost of the code combination was more than two times the comprehensive geometric mean cost of the single major claims reporting only the primary ''J1'' service), but that some of the code combinations met the CY 2014 frequency of ≥100 claims and ≥5 percent of the total claims volume for the primary service, including CPT codes 37221 and 37222 (Iliac artery revascularization (multiple vessels) with stent), 37229 and 37232 (Tibial/peroneal artery revascularization (multiple vessels) with atherectomy), and 37230 and 37232 (Tibial/peroneal artery revascularization (multiple vessels) with stent). The other four code combinations met the ≥5 percent volume threshold for the claims reporting the primary service, but in the relevant data year the frequency of these code combinations ranged from 13 to 22 cases, including CPT codes 37231 and 37232 (Tibial/peroneal artery revascularization (multiple vessels) with stent and atherectomy), 37229 and 37234 (Tibial/peroneal artery revascularization with atherectomy (multiple vessels) and with stent (multiple vessels)), 37231 and 37233 (Tibial/peroneal artery revascularization with stent and atherectomy (multiple vessels)), and 37231 and 37234 (Tibial/peroneal artery revascularization with stent (multiple vessels) and atherectomy). In no case did the geometric mean cost of the code combinations exceed the geometric mean cost of the single ''J1'' claims for the primary service alone by at least two times.

To qualify these code combinations for a complexity adjustment, the commenter recommended using a 1.5 instead of 2 times rule, patterned after the 50 percent multiple procedure reduction and based on the inability of hospitals to garner 100 percent efficiency when performing multiple procedures. The commenter stated that this slightly lower cost threshold would still be significant and, therefore, would appropriately allow complexity reassignment only for cases that are meaningfully underpaid under the threshold. (We received similar inquiries from other commenters regarding our application of the statutory ''2 times'' rule that are discussed below.)

In addition, the commenter recommended that CMS omit the CY 2014 required claim frequency threshold of greater than 100 claims with the specific combination of procedure codes. The commenter believed that the frequency threshold requiring that complex claims for a particular procedure code combination exceed 5 percent of the total volume of claims reporting the primary service alone is sufficient to ensure additional payment for only higher volume cases, and that an additional frequency threshold is not necessary. The commenter believed that the threshold should not depend on the procedures' frequency in prior years, which can fluctuate significantly.

The commenter asked for clarification regarding our treatment of add-on codes, recommending that all add-on codes assigned to the endovascular comprehensive APCs be equally eligible for complexity adjustments. The commenter noted that Table 10 of the CY OPPS/ASC 2014 final rule with comment period (78 FR 74889 through 74900) listed complexity adjustments for only a small number of add-on codes (for example, certain drug-eluting stent codes), and did not list complexity adjustments for any of the add-on codes for peripheral artery revascularization associated with procedures assigned to C–APCs 0083, 0229 and 0445. The commenter could not assess whether only some add-on code combinations were considered for complexity adjustments, or whether all combinations were considered but eliminated due to not meeting the cost or frequency criteria.

Similarly, another commenter requested additional information regarding application of the complexity criteria to all of the percutaneous coronary intervention (PCI) related code combinations in Table 10 of the CY 2014 OPPS/ASC final rule with comment period. In particular, the commenter was not sure whether the C9600–C9602 code combination required intervention in an additional vessel, whether a second stent in a new vessel is required, or whether one stent and rotational atherectomy together with an additional stent in the same vessel would qualify the procedure(s) for a complexity adjustment. The commenter believed that it would not be appropriate to apply an adjustment only when the second intervention was in a separate vessel, where a procedure involving placement of a stent in one vessel and a second stent in a branch of the same vessel would not be eligible for complexity adjustment, but placement of two stents in two separate vessels would be eligible because the resources required are potentially very similar. Regarding claims with more than one unit of HCPCS code C9606, the commenter was not sure whether the second revascularization procedure must involve a second episode of acute myocardial infarction (AMI) in the same outpatient encounter, or whether the complexity adjustment would apply when there is a single episode of AMI in two separate vessels or in the same vessel. Regardless of CMS' intent, the commenter questioned why interventions involving patients with AMI or total chronic occlusions are mapped to the same APCs as those that involve patients with lower levels of complexity.

Response: We begin by clarifying how we treated add-on codes, which are particularly common in the vascular family of comprehensive APCs, in modeling the CY 2014 payments for comprehensive APCs. The CPT Editorial Panel defines add-on codes as codes that describe procedures that are commonly carried out in addition to the primary procedure performed, listing add-on codes in Appendix D of the CPT codebook (2014 CPT Codebook Professional Edition, page xiv). The CPT codebook states that add-on codes are always performed in addition to the primary or ''base'' service or procedure and must never be reported as a stand-alone code. Add-on codes can also be Level II HCPCS codes, such as HCPCS codes C9601, C9603, C9605 and C9608, which are the drug-eluting stent insertion add-on codes that parallel the non-drug eluting stent insertion add-on CPT codes 92929, 92934, 92938 and 92944, respectively. In Table 15 of the CY 2014 OPPS/ASC final rule with comment period, we listed all add-on codes that are currently assigned to device-dependent APCs (78 FR 74944).

Historically and in most cases, the OPPS assigned add-on codes to the same APC as the base code and applied a multiple procedure reduction when

these codes were reported with the base code. Because add-on codes represent an extension or continuation of or are adjunctive to a primary service, beginning in CY 2014, we unconditionally packaged add-on codes, except for drug administration services, and add-on codes assigned to device-dependent APCs due to the delayed implementation of the comprehensive APC policy until CY 2015 (78 FR 74943). We discussed in that same final rule with comment period how this policy will improve the accuracy of OPPS ratesetting, as we would no longer be reliant on incorrectly coded single add-on code claims to set OPPS payment rates for add-on codes (78 FR 74942).

In the CY 2014 OPPS/ASC proposed rule, we proposed to unconditionally package add-on codes assigned to comprehensive APCs and to assign the procedures to status indicator ''N'' (78 FR 43559). They were not proposed as primary services assigned to status indicator ''J1'' because they would always be furnished adjunctive to another primary service assigned status indicator ''J1.'' We had not proposed a complexity adjustment, so there was no need to consider whether the multiple procedure claims that correctly report an add-on code should be promoted to a higher comprehensive APC.

In the CY 2014 OPPS/ASC final rule with comment period, we designated certain especially costly add-on codes as primary services assigned to status indicator ''J1.'' (We refer readers to Table 9 in the 2014 OPPS final rule with comment period (78 FR 74873 through 74883), which provided the APC assignments for HCPCS codes proposed to be assigned to status indicator ''J1'' for CY 2014 and were displayed for illustration.) Other add-on codes assigned to the device-dependent APCs illustrated as comprehensive APCs were packaged because of the CY 2014 policy to package most add-on codes under the OPPS. Because these packaged add-on codes were not sufficiently costly, they were not designated as primary ''J1'' services. As a result, for example, CPT codes 37222, 37232, 37233, and 37234 were not assigned status indicator ''J1'' in the CY 2014 OPPS/ASC final rule with comment period and instead were packaged similar to almost all of the other add-on codes. However, for CY 2014, because the implementation of the comprehensive APC policy was delayed until CY 2015, payment for services described by add-on codes assigned to a device-dependent APC are paid separately under the OPPS (78 FR 74943).

In response to the comments we received on the CY 2014 OPPS/ASC final rule with comment period, we considered ways to refine and simplify the complexity test when add-on codes that are currently assigned to the device-dependent APCs are reported with primary services proposed to be assigned to comprehensive APCs for CY 2015 in this proposed rule. Because services described by add-on codes are by definition adjunctive and furnished in addition to primary services assigned status indicator ''J1,'' we believe that the add-on codes should not be classified as primary services themselves because they cannot serve as the primary service provided to a patient. However, we continue to believe that we should recognize the additional cost and complexity of certain cases involving procedures described by certain especially costly add-on codes that are currently assigned to a device-dependent APC in CY 2014 because like certain combinations of ''J1'' procedure codes, primary service code and add-on code combinations can represent more complex and significantly more costly variations of the primary service. Therefore, we are proposing to revert to our original CY 2014 proposal for comprehensive APCs in which we would not consider any add-on codes that are currently assigned to device-dependent APCs as primary services assigned to status indicator ''J1'' (78 FR 43559). For CY 2015, we are proposing to allow certain combinations of primary service codes and especially costly add-on codes representing a more costly, complex variation of a procedure to trigger a complexity adjustment. We refer readers to section II.A.2.e.(3)(a) of this proposed rule for a detailed description of our proposed new methodology of evaluating primary service procedures reported in conjunction with add-on codes for complexity adjustments.

Also, in evaluating the comprehensive APC assignments based on CY 2013 claims data, we are proposing to consolidate and restructure the vascular comprehensive APCs, in addition to other APCs. We refer readers to section II.A.2.e.(3)(c) of this proposed rule for a discussion of the proposed reconfiguration, and to Addendum J to this proposed rule for the updated cost statistics and proposed complexity adjustments for the services to address the commenters' concerns. We are proposing complexity adjustments for several of the services indicated by the commenters, although some of the services continue to fail one or both of the proposed complexity criteria even under the proposed relaxed frequency and cost thresholds.

We agree with the commenters that we should revise the criteria for complexity adjustments. The delay in implementation afforded additional time for CMS and commenters to further analyze and consider the cost data. After further analysis and consideration of the public comments in response to the CY 2014 OPPS/ASC final rule with comment period, we believe that the complexity adjustment criteria in that final rule with comment period were too restrictive. None of the code combinations illustrated as qualifying for complexity adjustments in the CY 2014 OPPS/ASC final rule with comment period met all of the frequency and cost thresholds set forth in the CY 2014 OPPS/ASC final rule with comment period, and no code combinations would qualify under those criteria in CY 2015 using the CY 2013 cost data. However, we believe that especially costly and sufficiently frequent code combinations should qualify for a complexity adjustment.

In calculating the geometric mean costs for comprehensive APC services using the claims data for CY 2013, we noted that many of the comprehensive APCs in the same clinical family illustrated in the CY 2014 OPPS/ASC final rule with comment period had similar or overlapping comprehensive geometric mean costs, meaning that the geometric mean costs were close to one another or that the range of costs for procedures assigned to one comprehensive APC significantly overlapped the range of costs for procedures assigned to another comprehensive APC in the same clinical family. We are proposing to restructure and consolidate these comprehensive APCs, as further described in section II.A.2.e.(3)(c) of this proposed rule, in order to better distinguish service groups having different resource requirements. The proposed restructuring and consolidation eliminates the need for many of the complexity adjustments illustrated in the CY 2014 OPPS/ASC final rule with comment period because we are proposing to promote the primary service to a higher cost comprehensive APC for CY 2015 as compared to its illustrated comprehensive APC assignment for CY 2014. For example, for CY 2014, we illustrated complexity adjustments for the CPT code combinations 37228 and 35476, 37228 and 37220, 37228 and 37224, and multiple units of CPT code 37228 from C–APC 0083, the primary service CPT code 37228 was assigned with a comprehensive geometric mean cost of

$4,230 to C–APC 0104 with a comprehensive geometric mean cost of $8,554. For CY 2015, we are proposing to consolidate C–APCs 0104 and 0229, and to retain C–APC 0229. Considering our proposed initial assignment of CPT code 37228 to C–APC 0229, CPT code 37228 has a proposed CY 2015 geometric mean cost of $7,250 and C–APC 0229 has a CY 2015 proposed comprehensive geometric mean cost of approximately $9,998.

We agree with the commenters that complexity adjustments should be based upon criteria that demonstrate that the complex combination is both sufficiently frequent and sufficiently costly such that a payment adjustment is warranted within a similar clinical family, if possible. Our reliance on clinical comparisons of each code combination in determining the complexity adjustments illustrated for CY 2014 likely contributed to the difficulty experienced by commenters in reproducing the results of the policy. Accordingly, we further analyzed the cost data in order to identify viable alternatives for complexity adjustment criteria. For CY 2015, we are proposing the following new complexity adjustment criteria to evaluate HCPCS code combinations for complexity adjustments:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the ''2 times'' rule; that is, the comprehensive geometric mean cost of the ''complex'' code combination exceeds the comprehensive geometric mean cost of the lowest significant HCPCS code assigned to the originating comprehensive APC by at least 2 times (cost threshold). (''Significant'' means frequency >1000 claims, or frequency >99 claims and contributing at least 2 percent of the single major claims used to establish the originating comprehensive APC's geometric mean cost, including the claims reporting the complex code pair).

To illustrate how this second criterion is applied, for example, consider CPT code 33208 as the primary service reported in conjunction with HCPCS code C9600. CPT code 33208 is assigned to APC 0089. The lowest cost significant procedure assigned to APC 0089 is CPT code 33228, with a geometric mean cost of $8,669. There are 43 instances of the code combination of CPT code 33208 and HCPCS code C9600 in the CY 2013 claims data with a geometric mean cost of $21,914, which exceeds the geometric mean cost of CPT code 33228 ($8,669) by greater than two times ($21,914 > $17,338). Therefore, the code combination of CPT code 33208 and HCPCS code C9600 is assigned through a complexity adjustment to APC 0655, which is the next higher cost APC in the AIDCP clinical family of comprehensive APCs.

Whereas the criteria finalized in the CY 2014 OPPS/ASC final rule with comment period evaluated the marginal cost contribution of the additional procedure in comparison to the designated primary service alone (78 FR 74886), the proposed complexity adjustment criterion would employ our standard ''2 times'' rule (discussed in section III.B.2. of this proposed rule), comparing the costs associated with the code combination to the cost of other services assigned to the same comprehensive APC. We are proposing to make a complexity adjustment by reassigning a particular code combination to a higher cost comprehensive APC if there are 25 or more claims reporting the code combination in the data year and their comprehensive geometric mean cost exceeds the geometric mean cost of the lowest significant HCPCS code in the initial comprehensive APC by more than two times according to our standard ''2 times'' rule comparison. By ''significant HCPCS code,'' we mean our standard threshold for volume significance of the other codes being compared to the complex code combinations requiring a frequency >1000; or frequency >99 and contributing at least 2 percent of the single major claims used to establish the comprehensive APC geometric mean cost, including the claims reporting the complex code pair). We are proposing to apply the same test in assessing whether the complexity reassignment would create a ''2 times'' rule violation in the newly assigned comprehensive APC. However, if the claims comprise significant volume and violate the ''2 times'' rule cost differential, we are proposing to consider alternative comprehensive APC assignments, such as not making a complexity adjustment for the code combination, or not assigning the case to a higher cost APC within the same clinical family. In doing so, we also would require the complex code combination to be clinically similar to other procedures assigned to the comprehensive APC to which the complex code combination is reassigned. This is usually the case because complexity adjustments are confined to higher cost APCs within the same clinical family.

Comment: One commenter questioned the assignment of procedures within C–APCs 0083 (Level I Endovascular Procedures), 0229 (Level II Endovascular Procedures) and 0319 (Level IV Endovascular Procedures). The commenters believed that some of the procedures assigned to C–APC 0083 should be assigned to C–APC 0229, and stated that the adjunctive service rather than the primary service appeared to be driving the comprehensive APC mapping, specifically CPT code combinations 35476 and 37205, 35475 and 37205, 35471 and 37205, and 37220 and 37205.

Response: CPT code 37205 was deleted for CY 2014, and we are proposing to cross-walk CPT code 37205 to CPT code 37236 for CY 2015 based on the code descriptors. Until claims data are available for new codes, we are proposing to continue to make comprehensive APC assignments based on our best assessment of clinical and resource similarity (as we do for standard APC assignments), including examining the historical cost data for any predecessor code(s). Applying our proposed CY 2015 complexity adjustment criteria (significant volume of 25 or more complex claims and a ''2 times'' rule violation assessment relative to the lowest service within the originating comprehensive APC) would result in several complexity adjustments related to CPT code 37205, which are listed in Addendum J to this proposed rule (which is available via the Internet on the CMS Web site). We are proposing to provide these complexity adjustments when CPT code 37236 is reported in lieu of CPT code 37205 for each of these code combinations.

Comment: One commenter expressed concern regarding payment for certain anticoagulant and other drugs that are commonly furnished with services assigned to the endovascular family of comprehensive APCs, particularly Angiomax, Cleviprex, Recothrom and Agratroban. The commenter asked CMS to clarify that the proposed definition of a comprehensive APC includes adjunctive supplies, as well as adjunctive services. The commenter asserted that the proposed comprehensive APC payment methodology violates the OPPS statutory requirements for separate payment of specified covered outpatient drugs (SCODs) and the ''2 times'' rule. The commenter stated that CMS did not discuss application of the ''2 times'' rule in the statutory context, and noted that by design CMS selected primary procedures that were far more costly than the other services included in the comprehensive APC payment bundle. The commenter also asserted that the comprehensive APC policy is premature because it lacks clinical quality metrics and other safeguards for quality of outpatient care. The commenter

recommended alternative policies to incentivize cost-effectiveness, such as required data submission on hospital treatment decisions and making hospitals whole for use of cost-effective items and services including drugs. The commenter did not believe that Medicare's three hospital inpatient quality incentive programs include measures that are relevant for the comprehensive device-dependent procedures when they are furnished on an outpatient basis.

Response: In finalizing our CY 2014 policy to package drugs and biologicals that function as surgical supplies, we explained that CMS has the statutory authority to package the payment of any drugs, biologicals, and radiopharmaceuticals, including those that meet the statutory definition of a SCOD (78 FR 74931). Also, in finalizing our CY 2008 policy packaging all diagnostic radiopharmaceuticals and contrast agents, except those with pass-through status, we explained that CMS has the statutory authority to package the payment of any drugs, biologicals, and radiopharmaceuticals, including those that meet the statutory definition of a SCOD (72 FR 66766).

Our proposed definition of a comprehensive APC includes adjunctive supplies, as well as adjunctive services. In the CY 2014 OPPS/ASC final rule with comment period, we packaged all drugs, biologicals, and radiopharmaceuticals into the comprehensive APC payment, with the exception of certain drugs that are usually self-administered (SADs) and, therefore, not covered under Medicare Part B. We applied our existing policy that defines certain SADs as hospital supplies paid under the OPPS, such that these SADs would be included in the comprehensive APC payment bundle (78 FR 74868). For CY 2015, we are proposing to retain these aspects of our comprehensive APC policy. We are proposing to continue to package all drugs, biologicals, and radiopharmaceuticals into the comprehensive APC payment, including those SADs defined as hospital supplies, which are packaged in the OPPS (Medicare Benefit Policy Manual Chapter 15, Section 50.2.M, available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf*). Therefore, beginning in CY 2015, Angiomax, Cleviprex, Recothrom, Agratroban, and any other drugs, biologicals, and radiopharmaceuticals (except for SADs that are not considered hospital supplies) would be packaged when administered to a patient receiving a comprehensive service. There would be no separate payment for these non-pass-through drugs under the OPPS regardless of cost or any other factors.

We appreciate the commenters' concerns regarding ensuring the quality of hospital outpatient care. In section XIII. of this proposed rule, we discuss the Hospital OQR Program for CY 2015. To the extent that inpatient quality measures would not apply to the comprehensive services proposed for CY 2015, stakeholders should suggest specific measures that would be relevant in response to the section of the proposed rule dealing with hospital outpatient quality measures.

Automatic Implantable Cardiac Defibrillators and Pacemakers and Related Devices (AICDP)

Comment: One commenter asked CMS to create a comprehensive APC for Cardiac Resynchronization Therapy Pacemaker (CRT–P) in the absence of defibrillation (CPT code 33225) because the comprehensive APC packaging policy decreases payment relative to the multiple procedure reduction policy. The commenter requested a complexity adjustment when CPT code 33225 is reported in combination with CPT code 33206, 33207, 33208, or 33214 because of their high mean cost relative to all other pacemaker insertion procedures assigned to C–APC 0089 (Level III Insertion/replacement of Permanent Pacemaker) and C–APC 0655 (Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode).

Response: CPT code 33225 is an add-on code that was not assigned to status indicator ''J1'' in the CY 2014 OPPS/ASC final rule with comment period. For CY 2015, we are proposing to continue packaging this service, but to provide a complexity adjustment when the service is furnished in conjunction with CPT code 33207, 33208, or 33228 from C–APC 0089 to C–APC 0655 because these code combinations meet the proposed complexity adjustment criteria. The code combinations of CPT 33206 and 33225 and 33214 and 33225 meet the proposed cost threshold, but not the proposed frequency threshold and, therefore, we do not believe that we should provide complexity adjustments for these code combinations. Services that are reported fewer than 25 times a year do not comprise significant volume and are not sufficiently frequent service combinations in the context of the proposed comprehensive APC policy and proposed complexity adjustment criteria and, therefore, do not qualify for a complexity adjustment.

Neurostimulators

Comment: One commenter recommended splitting C–APC 0318 (Level II Implantation of Neurostimulator) to achieve a narrower cost range, placing vagal nerve and spinal cord stimulation in its own comprehensive APC and creating a separate comprehensive APC for other neurostimulator devices. The commenter also recommended reassigning CPT code 61886 to C–APC 0039 (Level I Implantation of Neurostimulator) to place all single generator procedures in the lower APC. In contrast, another commenter supported the complexity adjustments and the final comprehensive APC structure proposed for the neurostimulator family. The commenter stated in response to the CY 2014 OPPS/ASC final rule with comment period that appropriately differentiating payment rates for less-intensive pulse generator replacements from the more intensive initial system implants, which include placement of lead array(s), and also appropriately distinguishing payment rates between simpler less resource-intensive nerve stimulation procedures (for example, sacral nerve stimulation) and more complex resource-intensive nerve stimulation procedures (for example, spinal cord stimulation) is most appropriate. This commenter supported mapping the spinal cord stimulation system implants into C–APC 0318 because these implants have similar procedural complexity and resource utilization with the other procedures assigned to C–APC 0318.

Response: Some of the procedure codes assigned to the different neurostimulator comprehensive APCs illustrated for CY 2014 had similar or overlapping costs, in particular C–APCs 0040 and 0061, which had comprehensive geometric mean costs of $4,715 and $6,567 respectively. Having also updated the APCs based on CY 2013 cost data, for CY 2015, we are proposing to restructure the neurostimulator comprehensive APCs from four comprehensive APCs to three comprehensive APCs within a single series of APCs titled ''Neurostimulator and Related Procedures.'' We are proposing to begin this series with the non-comprehensive APC 0688 followed by the three levels of comprehensive APCs for neurostimulator procedures as follows: C–APC 0061 (Level II Neurostimulator and Related Procedures); C–APC 0039 (Level III Neurostimulator and Related Procedures); and C–APC 0318 (Level IV Neurostimulator and Related

Procedures). This proposed reconfiguration would establish groups of neurostimulator device-related services that have different and nonoverlapping cost ranges while applying the ''2 times'' rule, including several complexity adjustments for complex code combinations. We believe that the procedures proposed for assignment to C–APC 0318 for CY 2015 are clinically similar and similar in associated resources and, therefore, should be assigned to the same comprehensive APC. We also believe that CPT code 61886 more appropriately belongs in the higher level C–APC 0318 rather than C–APC 0039 based on its cost and complexity because it describes implantation of a cranial neurostimulator with connection to two or more electrode arrays. We do not believe that CPT code 61886 should be assigned to C–APC 0039 with less complex procedures.

Urogenital

Comment: Several commenters addressed the urogenital clinical family of comprehensive APCs. One commenter recommended that CMS exempt C–APC 0202 (Level VII Female Reproductive Procedures) from the comprehensive APC policy, due to the variability in geometric mean costs between cases with a single ''J1'' procedure and cases with multiple procedures furnished during the same surgical session (not otherwise specified). Alternatively, the commenter recommended different complexity criteria that would reassign the claims assigned to C–APC 0202 (Level VII Female Reproductive Procedures) to C–APC 0385 (Level I Urogenital Procedures) or C–APC 0386 (Level II Urogenital Procedures). The commenter suggested that we make a complexity adjustment for any claim with a service assigned to status indicator ''J1'' and at least two additional surgical procedures. The commenter also suggested the following possible alternative cost criteria: (1) Using percent of total device costs reported on a claim instead of the presence of a second service assigned status indicator ''J1'' to assess costliness; or (2) using a cost threshold of 1.5 instead of 2 times the cost of single claims for the primary service. The commenter also suggested a volume threshold of 50 instead of 100 claims. Finally, the commenter asked CMS to clarify how it determined uncommon clinical scenarios or extreme resource values for the complexity adjustment, and what data or information qualifies code combinations for reassignment.

Response: The commenter was not clear regarding which surgical procedures we should count or consider in determining complexity adjustments, for example specific services assigned status indicator ''J1'' that do not meet our proposed complexity criteria or surgical procedures that are not assigned to a comprehensive APC. It was not clear whether the commenters' recommendations were mutually exclusive, or recommended in some combination with one another. Also, it was not clear whether the commenter was suggesting that any two surgical procedures, even those not assigned to a comprehensive APC, should qualify a claim for complexity adjustment. As discussed above, for CY 2015, we are proposing different complexity adjustment criteria than those that were discussed in the CY 2014 OPPS/ASC final rule with comment period. As discussed above, for CY 2015, we are proposing less stringent complexity adjustment criteria—codes combinations, either two ''J1'' service codes or a ''J1'' service code and an add-on code that is eligible for a complexity adjustment must appear at least 25 times in the claims data and violate the 2 times rule. Extremely few claims involve the provision of more than two surgical procedures. Therefore, we do not believe that it is necessary or appropriate to complicate our proposed methodology by attempting to isolate marginal costs associated with other packaged surgical procedures. The complexity adjustment (both in the CY 2014 OPPS/ASC final rule with comment period and proposed in this CY 2015 OPPS/ASC proposed rule) would reassign all claims reporting a qualifying code combination, whether or not additional (third, fourth, or subsequent) services assigned to a comprehensive APC appear on the claim.

Stem Cell Transplant

Comment: One commenter recommended that CMS apply the comprehensive service concept to outpatient stem cell transplant (SCT) because the procedures occur in small volume and, due to their clinical nature, are almost always multiple procedure claims that are unusable under the standard ratesetting methodology. Specifically, the commenter requested that CMS create three comprehensive APCs for autologous outpatient SCT, where donor and recipient are the same; allogeneic-related outpatient SCT, where donor and recipient are biologically related; and allogeneic-unrelated transplants, where donor and recipient are biologically unrelated. The commenter stated that the costs associated with these three types of outpatient SCT vary significantly according to the donor search and acquisition costs, which are relatively modest for autologous outpatient SCT, $5,000 to $20,000 for allogeneic-related outpatient SCT, and $30,000 to $80,000 for allogeneic unrelated outpatient SCT. The commenter discussed how the low CCR associated with revenue code 0819 (Blood and Blood Products), which must be used to report donor search and acquisition charges, makes providers hesitant to report high donor charges and contributes to incorrectly coded claims.

Due to inaccuracies in cost reporting and exclusion of certain multiple procedure claims from ratesetting, the commenter believed that outpatient SCT payment is based on only a handful of incorrectly and incompletely coded single procedure claims. The commenter also believed that comprehensive APCs would improve payment adequacy by allowing the use of multiple procedure claims, provided CMS also create a separate and distinct CCR for donor search and acquisition charges so that they are not diluted by lower cost services. Alternatively, the commenter suggested that CMS require transplant centers to report their actual costs on outpatient claims for allogeneic SCT, and apply a default CCR of 1.0 for claims reporting the outpatient allogeneic procedure CPT code.

Response: For CY 2015, we are proposing to continue to pay separately for allogeneic transplantation procedures under APC 0111 (Blood Product Exchange) and APC 0112 (Apheresis and Stem Cell Procedures), with proposed rule geometric mean costs of approximately $1,127 and $3,064, respectively. Allogeneic harvesting procedures, which are performed not on the beneficiary but on a donor, cannot be paid separately under the OPPS because hospitals may bill and receive payment only for services provided to the Medicare beneficiary who is the recipient of the SCT and whose illness is being treated with the transplant. We stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60575) and in section 231.11 of Chapter 4 of the Medicare Claims Processing Manual (Pub. 100–04) that payment for allogeneic stem cell acquisition services (such as harvesting procedures and donor evaluation) is packaged into the payment for the transplant procedure (either the Medicare Severity—Diagnosis Related Group (MS–DRG) when the transplant is performed inpatient, or the APC when the transplant is performed outpatient). Hospitals should report all allogeneic

outpatient SCT acquisition charges on the recipient's outpatient claim as uncoded charges under revenue code 0819.

While converting the outpatient SCT APCs to comprehensive APCs would reduce to small degree the differential between the OPPS payment rate and the costs as represented in the public comment we received, it would only provide a relatively modest increase in payment, consistent with our previous data studies on this issue. We believe that we need to further examine the costs associated with this service and how they could best be captured for payment ratesetting purposes in the OPPS. This service remains low volume in the HOPD, but we will continue to monitor this issue and the volume of outpatient allogeneic transplant services.

General Comments on Comprehensive APCs

We also received several general comments that were not related to specific comprehensive APCs, as described below.

Comment: Many of the commenters recommended continued refinement of the comprehensive APC payment methodology to better identify and recognize the costs associated with complex services and patients. Some commenters suggested developing a list similar to the IPPS listing of complications and comorbidities (CCs) and major complications and comorbidities (MCCs) to identify complications and comorbidities associated with higher acuity patients in the outpatient setting. Other commenters suggested additional reimbursement when additional services, testing, or drugs are needed for patients with certain diagnoses (for example, end stage renal disease), or patients needing extended recovery time following a procedure in order to assess or treat comorbidities and ensure safe discharge. One commenter asserted that there is a critical difference between ''complex'' patients and ''complex'' procedures. The commenter stated that because the CY 2014 complexity adjustment test is multiple procedure-based rather than patient severity-based similar to the MS–DRG system, it is incredibly difficult for two procedures to meet the complexity test, particularly the 2 times rule requirement. The commenter believed that the cost threshold for the complexity test is not commensurate with the marginal payment increase.

Response: We believe that some of these commenters misunderstood the complexity adjustment criteria described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74886). The complexity adjustment criteria for the illustrated CY 2014 payment rates compared the comprehensive cost of the complex claims to the comprehensive cost of the single major claims for the primary service, not the comprehensive geometric mean cost of the initial comprehensive APC (78 FR 74886). However, for CY 2015, we believe that it would be more appropriate to use the 2 times rule, which compares the geometric mean cost of the code combination to the geometric mean cost of the lowest cost service assigned to the comprehensive APC with significant claims volume (>1000 single claims or >99 single and at least 2 percent of the total volume of single claims assigned to the APC). For further description of the 2 times rule, we refer readers to section III.B of this proposed rule. We agree with the commenter that the CY 2014 complexity adjustment cost criterion was too high of a threshold. Therefore, we are proposing to change the cost criterion for the complexity adjustment to twice the geometric mean cost of the lowest cost service having significant claims volume (as described above) in the APC.

Section 1833(t)(2) of the Act provides a procedure-based payment methodology for the OPPS, which is unlike the IPPS that makes payments based on both diagnoses and procedures. Currently OPPS payments are not based on patient severity or diagnosis like under the IPPS. The complexity adjustment test is procedure-based because the current OPPS payment methodology is procedure-based.

Comment: Several commenters recommended alternative complexity adjustment criteria, including a cost threshold of 1.5 instead of 2 times; a numeric volume test of 50 claims instead of 100, or omitting the numeric test; or basing the complexity adjustment on the number of surgical procedures on a claim (any claim with a service assigned to status indicator ''J1'' and at least two additional surgical procedures). Some commenters asserted generally that there should be tests other than the presence of two or more ''J1'' services on a claim. In addition, most of the commenters requested further information regarding how CMS determined complexity reassignments, including treatment of add-on codes. The commenters requested that CMS provide an addendum to the OPPS rule containing this information.

Response: As discussed above, for CY 2015, we are proposing less stringent frequency and cost thresholds for complexity adjustments. In addition, in response to public comments, we are presenting the proposed complexity adjustment cost information in a more detailed format in Addendum J to this proposed rule, rather than in long tables within the preamble text.

Comment: Several commenters requested that CMS maintain the device-dependent edits to ensure accurate cost reporting and attribution. One commenter requested in particular that CMS maintain the device-dependent edits for prostate cryoablation (CPT code 55873), percutaneous renal cryoablation, and other urogenital services to ensure accurate coding and payment. The commenter believed that comprehensive groupings will exacerbate reporting error if CMS discontinued the edits.

Response: We appreciate the commenters' concerns regarding accurate coding, and we understand that providers sometimes fail to itemize costs for packaged services separately on claims for the primary service(s). Our policy for comprehensive APCs reduces the need for separate itemization of packaged services by establishing clear packaging allocation rules at the hospital claim level. However, as we have observed in attempting to assess the marginal cost attributable to add-on codes and other packaged services, it is best if CMS can reliably identify and isolate these costs using claims data. Therefore, we are continuing to require hospitals to report all charges, including packaged charges, on claims to ensure all costs are reported and enable reliable cost estimation for packaged items and services. It is important that hospitals report all HCPCS codes consistent with their descriptors, CPT and/or CMS instructions, and correct coding principles, and that they report all charges for all services they furnish. We are proposing to package all device-dependent add-on codes, although we would evaluate their additional cost for purposes of applying the proposed complexity adjustment criteria.

Instead of eliminating all device-dependent edits, beginning in CY 2015, we are proposing to continue to require the reporting of a device code for all procedures that are currently assigned to a device-dependent APC in CY 2014. However to reduce hospitals' administrative burden, we are proposing that the device claims edit would be satisfied by the reporting of any medical device C-code currently listed among the device edits for the CY 2014 device-dependent APCs. A particular device C-code or codes would no longer be required for a particular procedure. We

refer readers to section IV.B. of this proposed rule for a detailed discussion of this proposed policy.

Comment: Several commenters recommended that CMS conduct a demonstration to confirm estimated savings, or delay the comprehensive APC payment policy pending further study.

Response: The comprehensive APC payment policy was finalized in the CY 2014 OPPS/ASC final rule with comment period with delayed implementation until CY 2015, and we do not believe that further delay is necessary. We also do not believe that a demonstration is necessary. We delayed implementation until CY 2015, and the public comments we received on the CY 2014 OPPS/ASC final rule with comment period do not reflect a need for fundamental changes to the policy or further delay in implementing the policy. The comprehensive APC policy is another step towards making the OPPS more of a prospective payment system and less of a fee schedule-type payment system with separate payment for each individually coded service. The rationale and statutory authority for the comprehensive APC policy was fully explained in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861). The public comments were largely supportive of the comprehensive APC payment methodology, provided we improve the transparency and reproducibility of the methodology and refine the complexity adjustments for the most costly, complex cases. These complex cases are mostly confined to three clinical families (endovascular, pacemaker/defibrillator, and neurostimulator). In response to comments and additional analysis including the new CY 2013 claims data, we are proposing to refine the complexity adjustment criteria discussed in section II.A.2.e.(3)(a) of this proposed rule.

(4) Proposed List of CY 2015 Comprehensive APCs and Summary of Proposed Policies

In summary, we are proposing to continue to define a comprehensive service as a classification for the provision of a primary service and all adjunctive services and supplies reported on the hospital Medicare Part B claim, with few exceptions, resulting in a single beneficiary copayment per claim. The comprehensive APC payment bundle would include all hospital services reported on the claim that are covered under Medicare Part B, except for the excluded services or services requiring separate payment by statute as noted above.

We are proposing to continue to define a clinical family of comprehensive APCs as a set of clinically related comprehensive APCs that represent different resource levels of clinically comparable services. We are proposing a total of 28 comprehensive APCs within 13 clinical families for CY 2015, as described below.

TABLE 7—CY 2015 PROPOSED COMPREHENSIVE APCS

Clinical family	Proposed CY 2015 C–APC	APC Title	Proposed CY 2015 APC geometric mean cost
AICDP	0090	Level II Pacemaker and Similar Procedures	$6,961.45
AICDP	0089	Level III Pacemaker and Similar Procedures	9,923.94
AICDP	0655	Level IV Pacemaker and Similar Procedures	17,313.08
AICDP	0107	Level I ICD and Similar Procedures	24,167.80
AICDP	0108	Level II ICD and Similar Procedures	32,085.90
BREAS	0648	Level IV Breast and Skin Surgery	7,674.20
CATHX	0427	Level II Tube or Catheter Changes or Repositioning	1,522.15
CATHX	0652	Insertion of Intraperitoneal and Pleural Catheters	2,764.85
ENTXX	0259	Level VII ENT Procedures	31,273.34
EPHYS	0084	Level I Electrophysiologic Procedures	922.84
EPHYS	0085	Level II Electrophysiologic Procedures	4,807.69
EPHYS	0086	Level III Electrophysiologic Procedures	14,835.04
EYEXX	0293	Level IV Intraocular Procedures	9,049.66
EYEXX	0351	Level V Intraocular Procedures	21,056.40
GIXXX	0384	GI Procedures with Stents	3,307.90
NSTIM	0061	Level II Neurostimulator & Related Procedures	5,582.10
NSTIM	0039	Level III Neurostimulator & Related Procedures	17,697.46
NSTIM	0318	Level IV Neurostimulator & Related Procedures	27,283.10
ORTHO	0425	Level V Musculoskeletal Procedures Except Hand and Foot	10,846.49
PUMPS	0227	Implantation of Drug Infusion Device	16,419.95
RADTX	0067	Single Session Cranial Stereotactic Radiosurgery	10,227.12
UROGN	0202	Level V Female Reproductive Procedures	4,571.06
UROGN	0385	Level I Urogenital Procedures	8,019.38
UROGN	0386	Level II Urogenital Procedures	14,549.04
VASCX	0083	Level I Endovascular Procedures	4,537.95
VASCX	0229	Level II Endovascular Procedures	9,997.53
VASCX	0319	Level III Endovascular Procedures	15,452.77
VASCX	0622	Level II Vascular Access Procedures	2,635.35

Clinical Family Descriptor Key:
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices
BREAS = Breast Surgery
CATHX = Tube/Catheter Changes
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology
EYEXX = Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
NSTIM = Neurostimulators

ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
UROGN = Urogenital Procedures
VASCX = Vascular Procedures

We are proposing a comprehensive APC payment methodology that adheres to the same basic principles as those finalized in the CY 2014 OPPS/ASC final rule with comment period, with the following proposed changes for CY 2015:

- We are proposing to reorganize and consolidate several of the current device-dependent APCs and CY 2014 comprehensive APCs;
- We are proposing to expand the comprehensive APC policy to include all device-dependent APCs and to create two other new comprehensive APCs (C–APC 0067 and C–APC 0351);
- We are proposing new complexity adjustment criteria:
- Frequency of 25 or more claims reporting the HCPCS code combination (the frequency threshold); and
- Violation of the ''2 times'' rule; that is, the comprehensive geometric mean cost of the complex code combination exceeds the comprehensive geometric mean cost of the lowest significant HCPCS code assigned to the comprehensive APC by more than 2 times (the cost threshold).

We are proposing to package all add-on codes, although we would evaluate claims reporting a single primary service code reported in combination with an applicable add-on code (we refer readers to Table 9 in this proposed rule for the list of applicable add-on codes) for complexity adjustments. We believe that the proposed criteria would improve transparency, reduce subjectivity in complexity assignments, reduce the beneficiary copayment for some cases, and reduce burden on other stakeholders in analyzing the comprehensive APC assignments. The proposed policies would result in 52 complexity adjustments listed in Addendum J to this proposed rule (which is available via the Internet on the CMS Web site).

f. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, multiple imaging services, and cardiac resynchronization therapy services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for a full discussion of the development of the composite APC methodology (72 FR 66611 through 66614 and 66650 through 66652) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) for more recent background.

For CY 2015, we are proposing to continue our composite APC payment policies for LDR prostate brachytherapy services, mental health services, and multiple imaging services, as discussed below. In addition, we note that we finalized a policy in the CY 2014 OPPS/ASC final rule with comment period to modify our longstanding policy to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (78 FR 74910 through 74912). For CY 2014, we created one new composite APC, entitled ''Extended Assessment and Management (EAM) Composite'' (APC 8009), to provide payment for all qualifying extended assessment and management encounters rather than recognize two levels of EAM composite APCs (78 FR 74910 through 74912). Under this policy, we allow any visits, a Level 4 or 5 Type A ED visit or a Level 5 Type B ED visit furnished by a hospital in conjunction with observation services of substantial duration to qualify for payment through EAM composite APC 8009. For CY 2015, we are proposing to pay for qualifying extended assessment and management services through composite APC 8009. For CY 2015, we also are proposing to discontinue our composite APC payment policies for cardiac electrophysiologic evaluation and ablation services (APC 8000), and to pay for these services through comprehensive APC 0086 (Level III Electrophysiologic Procedures), as presented in a proposal included under section II.A.2.e. of this proposed rule. As such, we are proposing to delete APC 8000 for CY 2015.

We note that we finalized a policy to discontinue and supersede the cardiac resynchronization therapy composite APC with comprehensive APC 0108 (Level II Implantation of Cardioverter-Defibrillators (ICDs)), as discussed in section II.A.2.e. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74902). For CY 2014, APC 0108 is classified as a composite APC, as discussed in the CY 2014 OPPS/ASC final rule with comment period, because comprehensive APCs were not made effective until CY 2015 (78 FR 74925). For CY 2015, with the implementation of our new comprehensive APC policy, we are proposing to effectuate the policy finalized in the CY 2014 OPPS/ASC final rule with comment period, and pay for cardiac resynchronization therapy services through comprehensive APC 0108 (proposed to be renamed ''Level II ICD and Similar Procedures''), which is discussed in section II.A.2.e. of this proposed rule.

(1) Extended Assessment and Management Composite APC (APC 8009)

Beginning in CY 2008, we included composite APC 8002 (Level I Extended Assessment and Management (EAM) Composite) and composite APC 8003 (Level II Extended Assessment and Management (EAM) Composite) in the OPPS to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (an extended visit). In most of these circumstances, observation services are furnished in conjunction with evaluation and management services as an integral part of a patient's extended encounter of care. From CY 2008 through CY 2013, in the circumstances when 8 or more hours of observation care was provided in conjunction with a high level visit, critical care, or direct referral for observation and is an integral part of a

patient's extended encounter of care, and was not furnished on the same day as surgery or post-operatively, a single OPPS payment was made for the observation and evaluation and management services through one of the two composite APCs as appropriate. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163 through 74165) for a full discussion of this longstanding policy for CY 2013 and prior years. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74910), we created one new composite APC, APC 8009 (Extended Assessment and Management (EAM) Composite), to provide payment for all qualifying extended assessment and management encounters rather than recognizing two levels of EAM composite services. Under the CY 2014 finalized policy, we no longer recognize composite APC 8002 or APC 8003. Beginning in CY 2014, we allowed services identified by the new single clinic visit HCPCS code G0463, a Level 4 or 5 Type A ED visit (CPT codes 99284 or 99285), a Level 5 Type B ED visit (HCPCS code G0384) or critical care (CPT code 99291) provided by a hospital in conjunction with observation services of substantial duration (8 or more hours) (provided the observation was not furnished on the same day as surgery or post-operatively) (78 FR 74910 through 74912) to qualify for payment through EAM composite APC 8009.

For CY 2015, we are proposing to continue our CY 2014 finalized policy to provide payment for all qualifying extended assessment and management encounters through composite APC 8009. As we did for CY 2014, for CY 2015, we are proposing to allow a clinic visit and certain high level ED visits furnished by a hospital in conjunction with observation services of substantial duration (8 or more hours) to qualify for payment through the EAM composite APC 8009 (provided the observation is not furnished on the same day as surgery or post-operatively). Specifically, we are proposing to continue to allow a clinic visit, a Level 4 or Level 5 Type A ED visit, or a Level 5 Type B ED visit furnished by a hospital or a direct referral for observation (identified by HCPCS code G0379) performed in conjunction with observation services of substantial duration to qualify for payment through composite APC 8009 (provided the observation is not furnished on the same day as surgery or post-operatively). We note that, for CY 2015, we are proposing to continue our current policy where one service code describes all clinic visits. We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74910 through 74912) for a full discussion of the creation of composite APC 8009.

As we noted in the CY 2014 OPPS/ASC final rule with comment period, the historical cost data used annually to calculate the geometric mean costs and payment rate for composite APC 8009 would not reflect the single clinic visit code that was new for CY 2014 (HCPCS code G0463) until our CY 2016 rulemaking cycle. We stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74910 through 74912) that when hospital claims data for the CY 2014 clinic and ED visit codes become available, we would calculate the geometric mean cost for the EAM composite APC 8009 using CY 2014 single and ''pseudo'' single procedure claims that meet each of the following criteria:

- The claims do not contain a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service 1 day earlier than the date of service associated with HCPCS code G0378. (By selecting these claims from single and ''pseudo'' single claims, we ensure that they would not contain a code for a service with status indicator ''T'' on the same date of service.)
- The claims contain 8 or more units of HCPCS code G0378 (Observation services, per hour.)
- The claims contain one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as HCPCS code G0378; or CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) provided on the same date of service or 1 day before the date of service for HCPCS code G0378.

Because we have no available cost data for HCPCS code G0463, for CY 2015, we are proposing to calculate the geometric mean cost for procedures assigned to APC 8009 using CY 2013 single and ''pseudo'' single procedure claims that met each of the following criteria:

- The claim did not contain a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service 1 day earlier than the date of service associated with HCPCS code G0378. (By selecting these claims from single and ''pseudo'' single claims, we assured that they would not contain a code for a service with status indicator ''T'' on the same date of service.)
- The claim contained 8 or more units of HCPCS code G0378 (Observation services, per hour.)
- The claim contained one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as HCPCS code G0378; or CPT code 99201 (Office or other outpatient visit for the evaluation and management of a new patient (Level 1)); CPT code 99202 (Office or other outpatient visit for the evaluation and management of a new patient (Level 2)); CPT code 99203 (Office or other outpatient visit for the evaluation and management of a new patient (Level 3)); CPT code 99204 (Office or other outpatient visit for the evaluation and management of a new patient (Level 4)); CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)); CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient (Level 1)); CPT code 99212 (Office or other outpatient visit for the evaluation and management of an established patient (Level 2)); CPT code 99213 (Office or other outpatient visit for the evaluation and management of an established patient (Level 3)); CPT code 99214 (Office or other outpatient visit for the evaluation and management of an established patient (Level 4)); CPT code 99215 (Office or other outpatient visit for the evaluation and management of an established patient (Level 5)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)); or HCPCS code G0384 (Type B emergency department visit (Level 5)); or CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) provided on the same date of service or 1 day before the date of service for HCPCS code G0378.

The proposed CY 2015 geometric mean cost resulting from this methodology for EAM composite APC 8009 is approximately $1,287.

(2) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC (APC 8001)

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the composite treatment service because there are separate codes that describe placement

of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex), which are generally present together on claims for the same date of service in the same operative session. In order to base payment on claims for the most common clinical scenario, and to further our goal of providing payment under the OPPS for a larger bundle of component services provided in a single hospital encounter, beginning in CY 2008, we began providing a single payment for LDR prostate brachytherapy when the composite service, reported as CPT codes 55875 and 77778, is furnished in a single hospital encounter. We base the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the geometric mean cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes that are not on the bypass list. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66652 through 66655) for a full history of OPPS payment for LDR prostate brachytherapy services and a detailed description of how we developed the LDR prostate brachytherapy composite APC.

For CY 2015, we are proposing to continue to pay for LDR prostate brachytherapy services using the composite APC payment methodology proposed and implemented for CY 2008 through CY 2014. That is, we are proposing to use CY 2013 claims reporting charges for both CPT codes 55875 and 77778 on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the proposed payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2014 practice, we are proposing not to use the claims that meet these criteria in the calculation of the geometric mean costs of procedures or services assigned to APC 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures) and APC 0651 (Complex Interstitial Radiation Source Application), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We are proposing to continue to calculate the geometric mean costs of procedures or services assigned to APCs 0163 and 0651 using single and ''pseudo'' single procedure claims. We continue to believe that this composite APC contributes to our goal of creating hospital incentives for efficiency and cost containment, while providing hospitals with the most flexibility to manage their resources. We also continue to believe that data from claims reporting both services required for LDR prostate brachytherapy provide the most accurate geometric mean cost upon which to base the proposed composite APC payment rate.

Using a partial year of CY 2013 claims data available for the CY 2015 OPPS/ASC proposed rule, we were able to use 379 claims that contained both CPT codes 55875 and 77778 to calculate the geometric mean cost of these procedures upon which the proposed CY 2015 payment rate for composite APC 8001 is based. The proposed geometric mean cost for composite APC 8001 for CY 2015 is approximately $3,669.

(3) Mental Health Services Composite APC (APC 0034)

For CY 2015, we are proposing to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

Specifically, we are proposing that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on one date of service based on the payment rates associated with the APCs for the individual services exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be assigned to APC 0034 (Mental Health Services Composite). We are proposing to continue to set the payment rate for APC 0034 at the same payment rate that we are proposing to establish for APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs), which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid one unit of APC 0034. Under this policy, the I/OCE would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 0176 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource-intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

(4) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital bills more than one imaging procedure within an imaging family on the same date of service, in order to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 12 of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74920 through 74924).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included in the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the

hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for composite APC payment, as well as any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2015, we are proposing to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy will reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. The proposed CY 2015 payment rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) are based on geometric mean costs calculated from a partial year of CY 2013 claims available for the proposed rule that qualified for composite payment under the current policy (that is, those claims with more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we used to calculate the final CY 2013 and CY 2014 geometric mean costs for these composite APCs, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, pursuant to our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site) and are discussed in more detail in section II.A.1.b. of this proposed rule.

For this CY 2015 OPPS/ASC proposed rule, we were able to identify approximately 636,000 ''single session'' claims out of an estimated 1.6 million potential composite APC cases from our ratesetting claims data, approximately 40 percent of all eligible claims, to calculate the proposed CY 2015 geometric mean costs for the multiple imaging composite APCs.

Table 8 below lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC geometric mean costs for CY 2015.

TABLE 8—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1—Ultrasound	
CY 2015 APC 8004 (ultrasound composite)	**CY 2015 approximate APC geometric mean cost = $299**
76604	Us exam, chest.
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76775	Us exam abdo back wall, lim.
76776	Us exam k transpl w/Doppler.
76831	Echo exam, uterus.
76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.
Family 2—CT and CTA With and Without Contrast	
CY 2015 APC 8005 (CT and CTA without contrast composite)*	**CY 2015 approximate APC geometric mean cost = $335**
70450	Ct head/brain w/o dye.
70480	Ct orbit/ear/fossa w/o dye.
70486	Ct maxillofacial w/o dye.
70490	Ct soft tissue neck w/o dye.
71250	Ct thorax w/o dye.
72125	Ct neck spine w/o dye.
72128	Ct chest spine w/o dye.
72131	Ct lumbar spine w/o dye.
72192	Ct pelvis w/o dye.
73200	Ct upper extremity w/o dye.
73700	Ct lower extremity w/o dye.
74150	Ct abdomen w/o dye.
74261	Ct colonography, w/o dye.
74176	Ct angio abd & pelvis.
CY 2015 APC 8006 (CT and CTA with contrast composite)	**CY 2015 Approximate APC geometric mean cost = $558**
70487	Ct maxillofacial w/dye.
70460	Ct head/brain w/dye.
70470	Ct head/brain w/o & w/dye.
70481	Ct orbit/ear/fossa w/dye.
70482	Ct orbit/ear/fossa w/o & w/dye.
70488	Ct maxillofacial w/o & w/dye.
70491	Ct soft tissue neck w/dye.
70492	Ct sft tsue nck w/o & w/dye.
70496	Ct angiography, head.
70498	Ct angiography, neck.
71260	Ct thorax w/dye.

TABLE 8—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

71270	Ct thorax w/o & w/dye.
71275	Ct angiography, chest.
72126	Ct neck spine w/dye.
72127	Ct neck spine w/o & w/dye.
72129	Ct chest spine w/dye.
72130	Ct chest spine w/o & w/dye.
72132	Ct lumbar spine w/dye.
72133	Ct lumbar spine w/o & w/dye.
72191	Ct angiograph pelv w/o & w/dye.
72193	Ct pelvis w/dye.
72194	Ct pelvis w/o & w/dye.
73201	Ct upper extremity w/dye.
73202	Ct uppr extremity w/o & w/dye.
73206	Ct angio upr extrm w/o & w/dye.
73701	Ct lower extremity w/dye.
73702	Ct lwr extremity w/o & w/dye.
73706	Ct angio lwr extr w/o & w/dye.
74160	Ct abdomen w/dye.
74170	Ct abdomen w/o & w/dye.
74175	Ct angio abdom w/o & w/dye.
74262	Ct colonography, w/dye.
75635	Ct angio abdominal arteries.
74177	Ct angio abd & pelv w/contrast.
74178	Ct angio abd & pelv 1 + regns.

* If a ''without contrast'' CT or CTA procedure is performed during the same session as a ''with contrast'' CT or CTA procedure, the I/OCE would assign APC 8006 rather than APC 8005.

Family 3—MRI and MRA With and Without Contrast

CY 2015 APC 8007 (MRI and MRA without contrast composite) *	**CY 2015 approximate APC geometric mean cost = $640**
70336	Magnetic image, jaw joint.
70540	Mri orbit/face/neck w/o dye.
70544	Mr angiography head w/o dye.
70547	Mr angiography neck w/o dye.
70551	Mri brain w/o dye.
70554	Fmri brain by tech.
71550	Mri chest w/o dye.
72141	Mri neck spine w/o dye.
72146	Mri chest spine w/o dye.
72148	Mri lumbar spine w/o dye.
72195	Mri pelvis w/o dye.
73218	Mri upper extremity w/o dye.
73221	Mri joint upr extrem w/o dye.
73718	Mri lower extremity w/o dye.
73721	Mri jnt of lwr extre w/o dye.
74181	Mri abdomen w/o dye.
75557	Cardiac mri for morph.
75559	Cardiac mri w/stress img.
C8901	MRA w/o cont, abd.
C8904	MRI w/o cont, breast, uni.
C8907	MRI w/o cont, breast, bi.
C8910	MRA w/o cont, chest.
C8913	MRA w/o cont, lwr ext.
C8919	MRA w/o cont, pelvis.
C8932	MRA, w/o dye, spinal canal.
C8935	MRA, w/o dye, upper extr.
CY 2015 APC 8008 (MRI and MRA with contrast composite)	**CY 2015 Approximate APC geometric mean cost = $958**
70549	Mr angiograph neck w/o & w/dye.
70542	Mri orbit/face/neck w/dye.
70543	Mri orbt/fac/nck w/o & w/dye.
70545	Mr angiography head w/dye.
70546	Mr angiograph head w/o & w/dye.
70547	Mr angiography neck w/o dye.
70548	Mr angiography neck w/dye.
70552	Mri brain w/dye.
70553	Mri brain w/o & w/dye.
71551	Mri chest w/dye.
71552	Mri chest w/o & w/dye.
72142	Mri neck spine w/dye.
72147	Mri chest spine w/dye.
72149	Mri lumbar spine w/dye.
72156	Mri neck spine w/o & w/dye.
72157	Mri chest spine w/o & w/dye.
72158	Mri lumbar spine w/o & w/dye.
72196	Mri pelvis w/dye.
72197	Mri pelvis w/o & w/dye.
73219	Mri upper extremity w/dye.
73220	Mri uppr extremity w/o & w/dye.

TABLE 8—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

73222	Mri joint upr extrem w/dye.
73223	Mri joint upr extr w/o & w/dye.
73719	Mri lower extremity w/dye.
73720	Mri lwr extremity w/o & w/dye.
73722	Mri joint of lwr extr w/dye.
73723	Mri joint lwr extr w/o & w/dye.
74182	Mri abdomen w/dye.
74183	Mri abdomen w/o & w/dye.
75561	Cardiac mri for morph w/dye.
75563	Card mri w/stress img & dye.
C8900	MRA w/cont, abd.
C8902	MRA w/o fol w/cont, abd.
C8903	MRI w/cont, breast, uni.
C8905	MRI w/o fol w/cont, brst, un.
C8906	MRI w/cont, breast, bi.
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest.
C8911	MRA w/o fol w/cont, chest.
C8912	MRA w/cont, lwr ext.
C8914	MRA w/o fol w/cont, lwr ext.
C8918	MRA w/cont, pelvis.
C8920	MRA w/o fol w/cont, pelvis.
C8931	MRA, w/dye, spinal canal.
C8933	MRA, w/o&w/dye, spinal canal.
C8934	MRA, w/dye, upper extremity.
C8936	MRA, w/o&w/dye, upper extr.

* If a ''without contrast'' MRI or MRA procedure is performed during the same session as a ''with contrast'' MRI or MRA procedure, the I/OCE would assign APC 8008 rather than APC 8007.

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or bundle of specific services for a particular patient. The OPPS packages payment for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more expensive than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which often results if separate payment is provided for the items.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. Over the last 15 years, as we have refined our understanding of the OPPS as a prospective payment system, we have packaged numerous services that we originally paid as primary services. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b), including the five packaging policies that were added in CY 2014 (78 FR 74925). Our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided in the OPPS to determine which OPPS services can be packaged to achieve the objective of advancing the OPPS as a prospective payment system.

We have examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment of the primary service they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. In general, in this CY 2015 OPPS/ASC proposed rule, we are proposing to package the costs of selected HCPCS codes into payment for services reported with other HCPCS codes where we believe that one code reported an item

or service that was integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by another HCPCS code. Below we discuss categories and classes of items and services that we are proposing to package beginning in CY 2015. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), and the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925).

b. Proposed Revisions of a Packaging Policy Established in CY 2014—Procedures Described by Add-On Codes

In the CY 2014 OPPS/ASC final rule with comment period, we packaged add-on codes in the OPPS, with the exception of add-on codes describing drug administration services (78 FR 74943; 42 CFR 419.2(b)(18)). With regard to the packaging of add-on procedures that use expensive medical devices, we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74943) that the most expensive medical devices used in procedures to insert or implant devices in the hospital outpatient setting are included in procedures that are assigned to comprehensive APCs. Comprehensive APCs are discussed in section II.A.2.e. of this proposed rule. In the CY 2014 OPPS/ASC final rule with comment period, we discussed the comprehensive APC policy, which we adopted, with modification, but delayed the implementation of, until CY 2015 (78 FR 74864). We stated that for CY 2014, we would continue to pay separately for only those add-on codes (except for drug administration add-on codes) that were assigned to device-dependent APCs in CY 2014, but that, after CY 2014, these device-dependent add-on codes would be paid under the comprehensive APC policy. According to the proposed changes to the comprehensive APC policy described in section II.A.2.e. of this proposed rule, we are proposing to package all of the procedures described by add-on codes that are currently assigned to device-dependent APCs, which will be replaced by comprehensive APCs. The device-dependent add-on codes that are separately paid in CY 2014 that we are proposing to package in CY 2015 are listed below in Table 9.

TABLE 9—ADD-ON CODES ASSIGNED TO DEVICE-DEPENDENT APCS FOR CY 2014 THAT ARE PROPOSED TO BE PACKAGED IN CY 2015

CY 2014 Add-on code	Short descriptor	CY 2014 APC
19297	Place breast cath for rad	0648
33225	L ventric pacing lead add-on	0655
37222	Iliac revasc add-on	0083
37223	Iliac revasc w/stent add-on	0083
37232	Tib/per revasc add-on	0083
37233	Tib/per revasc w/ather add-on	0229
37234	Revsc opn/prq tib/pero stent	0083
37235	Tib/per revasc stnt & ather	0083
37237	Open/perq place stent ea add	0083
37239	Open/perq place stent ea add	0083
49435	Insert subq exten to ip cath	0427
92921	Prq cardiac angio addl art	0083
92925	Prq card angio/athrect addl	0082
92929	Prq card stent w/angio addl	0104
92934	Prq card stent/ath/angio	0104
92938	Prq revasc byp graft addl	0104
92944	Prq card revasc chronic addl	0104
92998	Pul art balloon repr precut	0083
C9601	Perc drug-el cor stent bran	0656
C9603	Perc d-e cor stent ather br	0656
C9605	Perc d-e cor revasc t cabg b	0656
C9608	Perc d-e cor revasc chro add	0656

c. Proposed Packaging Policies for CY 2015

(1) Ancillary Services

Under the OPPS, we currently pay separately for certain ancillary services. Some of these ancillary services are currently assigned to status indicator ''X,'' which is defined as ''ancillary services,'' but some other ancillary services are currently assigned to status indicators other than ''X.'' This is because the current use of status indicator ''X'' in the OPPS is incomplete and imprecise. Some procedures and services that are ancillary, for example, a chest X-ray, are assigned to an APC with services assigned status indicator ''S.'' We reviewed all of the covered HOPD services provided in the HOPD and identified those that are commonly performed when provided with other HOPD services, and also provided as ancillary to a primary service in the HOPD. These ancillary services that we have identified are primarily minor diagnostic tests and procedures that are often performed with a primary service, although there are instances where hospitals provide such services alone and without another primary service during the same encounter.

As discussed in section II.A.3.a. of this proposed rule, our intent is that the OPPS be more of a prospective payment system with expanded packaging of items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service. Given that the longstanding OPPS policy is to package items and services that are integral, ancillary, supportive, dependent, or adjunctive to a primary service, we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74945) that we believe that ancillary services should be packaged when they are performed with another service, but should continue to be separately paid when performed alone. We indicated that this packaging approach is most consistent with a prospective payment system and the regulation at 42 CFR 419.2(b) that packages many ancillary services into

primary services while preserving separate payment for those instances in which one of these ancillary services is provided alone (not with any other service paid under the OPPS) to a hospital outpatient. We did not finalize the ancillary packaging policy for CY 2014 because we believed that further evaluation was necessary (78 FR 74946).

In this proposed rule, we are proposing to conditionally package certain ancillary services for CY 2015. Specifically, we are proposing to limit the initial set of APCs that contain conditionally packaged services to those ancillary service APCs with a proposed geometric mean cost of less than or equal to $100 (prior to application of the conditional packaging status indicator). We are limiting this initial set of packaged ancillary service APCs to those with a proposed geometric mean cost of less than or equal to $100 in response to public comments on the CY 2014 ancillary service packaging proposal in which commenters expressed concern that certain low volume but relatively costly ancillary services would have been packaged into high volume but relatively inexpensive primary services (for example, a visit) (74 FR 74945). We note that the proposed $100 geometric mean cost limit for selecting this initial group of conditionally packaged ancillary service APCs is less than the geometric mean cost of APC 0634, which contains the single clinic visit code G0463, which is a single payment rate for clinic visits beginning in CY 2014, and has a CY 2015 OPPS/ASC proposed rule geometric mean cost of $102.68. This proposed $100 geometric mean cost limit is part of the methodology of selecting the initial set of conditionally packaged ancillary service APCs under this proposed packaging policy. It is not meant to represent a threshold above which ancillary services will not be packaged, but as a basis for selecting this initial set of APCs, which will likely be updated and expanded in future years. In future years, we may package ancillary services assigned to APCs with geometric mean costs higher than $100. In addition, geometric mean costs can change over time. A change in the geometric mean cost of any of the proposed APCs above $100 in future years would not change the conditionally packaged status of services assigned to the APCs selected in 2015 in a future year. We will continue to consider these APCs to be conditionally packaged. However, we will review the conditionally packaged status of ancillary services annually.

We are proposing to exclude certain services from this packaging policy even though they are assigned to APCs with a geometric mean cost of ≤ $100. Preventive services will continue to be paid separately, and includes the following services listed in Table 10 below that would otherwise be packaged under this policy.

TABLE 10—PREVENTIVE SERVICES EXEMPTED FROM THE ANCILLARY SERVICE PACKAGING POLICY

HCPCS Code	Short descriptor	APC
76977	Us bone density measure	0340
77078	Ct bone density axial	0260
77080	Dxa bone density axial	0261
77081	Dxa bone density/peripheral	0260
G0117	Glaucoma scrn hgh risk direc	0260
G0118	Glaucoma scrn hgh risk direc	0230
G0130	Single energy x-ray study	0230
G0389	Ultrasound exam aaa screen	0265
G0404	Ekg tracing for initial prev	0450
Q0091	Obtaining screen pap smear	0450

In addition, we are not proposing to package certain psychiatry and counseling-related services as we see similarities to a visit and, at this time, do not consider them to be ancillary services. We also are not proposing to package certain low cost drug administration services as we are examining various alternative payment policies for drug administration services, including the associated drug administration add-on codes.

Finally, we are proposing to delete status indicator ''X'' (Ancillary Services) because the majority of the services assigned to status indicator ''X'' are proposed to be assigned to status indicator ''Q1'' (STV-Packaged Codes). For the services that are currently assigned status indicator ''X'' that are not proposed to be conditionally packaged under this policy, we will assign those services status indicator ''S'' (Procedure or Service, Not Discounted When Multiple), indicating separate payment and that the services are not subject to the multiple procedure reduction. The APCs that we are proposing for conditional packaging as ancillary services in CY 2015 are listed below in Table 11.

TABLE 11—APCS FOR PROPOSED CONDITIONALLY PACKAGED ANCILLARY SERVICES FOR CY 2015

APC	Proposed CY 2015 OPPS geometric mean cost	Proposed CY 2015 OPPS SI	Group title
0012	$76.29	Q1	Level I Debridement & Destruction.
0060	20.64	Q1	Manipulation Therapy.
0077	52.08	Q1	Level I Pulmonary Treatment.
0099	81.27	Q1	Electrocardiograms/Cardiography.
0215	104.63	Q1	Level I Nerve and Muscle Services.
0230	55.00	Q1	Level I Eye Tests & Treatments.
0260	62.43	Q1	Level I Plain Film Including Bone Density Measurement.
0261	99.85	Q1	Level II Plain Film Including Bone Density Measurement.
0265	96.51	Q1	Level I Diagnostic and Screening Ultrasound.
0340	64.78	Q1	Level II Minor Procedures.

TABLE 11—APCS FOR PROPOSED CONDITIONALLY PACKAGED ANCILLARY SERVICES FOR CY 2015—Continued

APC	Proposed CY 2015 OPPS geometric mean cost	Proposed CY 2015 OPPS SI	Group title
0342	56.99	Q1	Level I Pathology.
0345	78.83	Q1	Level I Transfusion Laboratory Procedures.
0364	42.69	Q1	Level I Audiometry.
0365	123.21	Q1	Level II Audiometry.
0367	166.31	Q1	Level I Pulmonary Tests.
0420	130.93	Q1	Level III Minor Procedures.
0433	190.21	Q1	Level II Pathology.
0450	29.91	Q1	Level I Minor Procedures.
0624	83.61	Q1	Phlebotomy and Minor Vascular Access Device Procedures.
0690	37.25	Q1	Level I Electronic Analysis of Devices.
0698	106.17	Q1	Level II Eye Tests & Treatments.

The HCPCS codes that we are proposing to conditionally package as ancillary services for CY 2015 are displayed in Addendum B to this CY 2015 OPPS/ASC proposed rule. The supporting documents for the proposed rule are available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

We also are proposing to revise the regulations at 42 CFR 419.2(b)(7) to replace the phrase ''Incidental services such as venipuncture'' with ''Ancillary services'' to more accurately reflect the proposed packaging policy discussed above.

We are inviting public comments on these proposals.

(2) Prosthetic Supplies

We have a longstanding policy of providing payment under the OPPS for implantable DME, implantable prosthetics, and medical and surgical supplies, as provided at sections 1833(t)(1)(B)(i) and (t)(1)(B)(iii) of the Act and 42 CFR 419.2(b)(4), (b)(10), and (b)(11). In the CY 2014 OPPS/ASC final rule with comment period, we clarified that medical and surgical supplies under § 419.2(b)(4) include (but are not limited to) all supplies on the DMEPOS Fee Schedule except prosthetic supplies (78 FR 74947). Under 42 CFR 419.22(j), prosthetic supplies are currently excluded from payment under the OPPS and are paid under the DMEPOS Fee Schedule, even when provided in the HOPD. However, under section 1833(t)(1)(B)(i) of the Act, the Secretary has the authority to designate prosthetic supplies provided in the hospital outpatient setting as covered OPD services payable under the OPPS.

As mentioned above, implantable prosthetic devices are packaged in the OPPS under 42 CFR 419.2(b)(11). It is common for implantable prosthetic devices to be provided as a part of a device system. Such device systems include the implantable part or parts of the overall device system and also certain nonimplantable prosthetic supplies that are integral to the overall function of the medical device, part of which is implanted and part of which is external to the patient. These prosthetic supplies are integral to the implantable prosthetic because typically shortly after the surgical procedure to implant the implantable prosthetic device in the hospital, the surgeon and/or his or her colleagues will have to attach, fit, and program certain prosthetic supplies that are not surgically implanted into the patient but are a part of a system and that are essential to the overall function of an implanted device. Because these supplies are integral to the overall function of the implanted prosthetic, and because, as mentioned above, we package in the OPPS items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service, we believe that it is most consistent with a prospective payment system to package the payment of prosthetic supplies (along with the implantable prosthetic device) into the surgical procedure that implants the prosthetic device, as all of the components are typically necessary for the performance of the system and the hospital typically purchases the system as a single unit. Patients requiring replacement supplies at a time later than the initial surgical procedure and outside of the hospital would obtain them as they typically do from a DMEPOS supplier with payment for such supplies made under the DMEPOS Fee Schedule.

In addition to prosthetic supplies that are components of device systems, part of which are implanted, many other prosthetic supplies on the DMEPOS fee schedule are typical medical and surgical supplies and of the type that are packaged in the OPPS under § 419.2(b)(4). Consistent with our change from status indicator ''A'' to ''N'' for all nonprosthetic DMEPOS supplies in the CY 2014 OPPS final rule with comment period (78 FR 74947), we are proposing to package and change the status indicator from ''A'' to ''N'' for all DMEPOS prosthetic supplies. With this proposed change, all medical and surgical supplies would be packaged in the OPPS.

Therefore, we are proposing to delete ''prosthetic supplies'' from the regulations at § 419.22(j) because we are proposing that prosthetic supplies be packaged covered OPD services in the OPPS for CY 2015. Prosthetic supplies provided in the HOPD would be included in ''medical and surgical supplies'' (as are all other supplies currently provided in the HOPD) under § 419.2(b)(4). The HCPCS codes for prosthetic supplies that we are proposing to package for CY 2015 are displayed in Addendum B to this CY 2015 OPPS/ASC proposed rule. The supporting documents for the proposed rule, including but not limited to these Addenda, are available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

We are inviting public comments on these proposals.

4. Proposed Calculation of OPPS Scaled Payment Weights

For CY 2015, we are proposing to calculate the relative payment weights for each APC shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) using the APC costs discussed in sections II.A.1. and II.A.2. of this proposed rule. Prior to CY 2007, we standardized all the relative payment weights to APC 0601 (Mid-Level Clinic Visit) because mid-level clinic visits

were among the most frequently performed services in the hospital outpatient setting. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601 to derive the relative payment weight for each APC.

Beginning with the CY 2007 OPPS (71 FR 67990), we standardized all of the relative payment weights to APC 0606 (Level 3 Clinic Visits) because we deleted APC 0601 as part of the reconfiguration of the clinic visit APCs. We selected APC 0606 as the base because it was the mid-level clinic visit APC (that is, Level 3 of five levels). For the CY 2013 OPPS (77 FR 68283), we established a policy of using geometric mean-based APC costs rather than median-based APC costs to calculate relative payment weights. For CY 2015, we are proposing to continue this policy.

For the CY 2014 OPPS, we standardized all of the relative payment weights to clinic visit APC 0634 as discussed in section VII. of this proposed rule. For CY 2015, we are proposing to continue this policy to maintain consistency in calculating unscaled weights that represent the cost of some of the most frequently provided services. We are proposing to assign APC 0634 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the proposed geometric mean cost for APC 0634 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to base the proposed relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2015 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we are proposing to compare the estimated aggregate weight using the CY 2014 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2015 unscaled relative payment weights.

For CY 2014, we multiplied the CY 2014 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2013 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2015, we are proposing to apply the same process using the proposed CY 2015 unscaled relative payment weights rather than scaled relative payment weights. We are proposing to calculate the weight scaler by dividing the CY 2014 estimated aggregate weight by the proposed CY 2015 estimated aggregate weight. The service-mix is the same in the current and prospective years because we use the same set of claims for service volume in calculating the aggregate weight for each year. We note that the CY 2014 OPPS scaled relative weights incorporate the estimated payment weight from packaged laboratory tests previously paid at CLFS rates.

For a detailed discussion of the weight scaler calculation, we refer readers to the OPPS claims accounting document available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

We are proposing to include estimated payments to CMHCs in our comparison of the estimated unscaled relative payment weights in CY 2015 to the estimated total relative payment weights in CY 2014 using CY 2013 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we adjusted the proposed CY 2015 unscaled relative payment weights for purposes of budget neutrality. The proposed CY 2015 unscaled relative payment weights were adjusted by multiplying them by a weight scaler of 1.3220 to ensure that the proposed CY 2015 relative payment weights are budget neutral.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act states that ''Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.'' Therefore, the cost of those SCODs (as discussed in section V.B.3. of this proposed rule) is included in the budget neutrality calculations for the CY 2015 OPPS.

The proposed CY 2015 unscaled relative payment weights listed in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) incorporate the proposed recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28087), consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2014 forecast of the FY 2015 market basket increase, the proposed FY 2015 IPPS market basket update is 2.7 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(iv) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2015.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). 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. In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28087), we discussed the calculation of the proposed MFP adjustment for FY 2015, which is 0.4 percentage point.

We are proposing that if more recent data become subsequently available after the publication of this proposed rule (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 CY 2015 market basket update and the MFP adjustment, components in

calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2015 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that, for each of years 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2015, section 1833(t)(3)(G)(iv) of the Act provides a 0.2 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(iv) of the Act, we are proposing to apply a 0.2 percentage point reduction to the OPD fee schedule increase factor for CY 2015.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we are proposing to apply an OPD fee schedule increase factor of 2.1 percent for the CY 2015 OPPS (which is 2.7 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.4 percentage point MFP adjustment, and less the 0.2 percentage point additional adjustment).

Hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

In this proposed rule, we are proposing to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (*6*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2015, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(iv) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by an additional 0.2 percentage point for CY 2015.

To set the OPPS conversion factor for CY 2015, we are proposing to increase the CY 2014 conversion factor of $72.672 by 2.1 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing to further adjust the conversion factor for CY 2015 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We are proposing to calculate an overall proposed budget neutrality factor of 0.9998 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2015 IPPS wage indexes to those payments using the FY 2014 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For CY 2015, we are proposing to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

For CY 2015, we are proposing to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule. We are proposing to calculate a CY 2015 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2015 payments under section 1833(t) of the Act, including the proposed CY 2015 cancer hospital payment adjustment, to estimated CY 2015 total payments using the CY 2014 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The CY 2015 estimated payments applying the proposed CY 2015 cancer hospital payment adjustment are identical to estimated payments applying the CY 2014 final cancer hospital payment adjustment. Therefore, we are proposing to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

For this proposed rule, we estimate that pass-through spending for drugs, biologicals, and devices for CY 2015 would equal approximately $15.5 million, which represents 0.03 percent of total projected CY 2015 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.02 percent estimate of pass-through spending for CY 2014 and the 0.03 percent estimate of pass-through spending for CY 2015, resulting in a proposed adjustment for CY 2015 of 0.01 percent. Finally, estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2015.

The proposed OPD fee schedule increase factor of 2.1 percent for CY 2015 (that is, the estimate of the hospital inpatient market basket percentage increase of 2.7 percent less the proposed 0.4 percentage point MFP adjustment and less the 0.2 percentage point required under section 1833(t)(3)(F)(ii) of the Act), the required proposed wage index budget neutrality adjustment of approximately 0.9998, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of 0.01 percent of projected OPPS spending for the difference in the pass-through spending result in a proposed conversion factor for CY 2015 of $74.176.

Hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we are proposing to make all other adjustments discussed above, but using a reduced OPD fee schedule update factor of 0.1 percent (that is, the proposed OPD fee schedule increase factor of 2.1 percent further reduced by 2.0 percentage points). This results in a proposed reduced conversion factor for CY 2015 of $72.692 for hospitals that fail to meet the Hospital OQR requirements (a difference of −$1.484 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2015, we are proposing to use a conversion factor of $74.176 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. We are proposing to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (*6*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2015 to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(iv) of the Act. We are proposing to use a reduced conversion factor of $72.692 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements.

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to ''determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner'' (codified at 42 CFR 419.43(a)). This portion of the

OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). Therefore, we are proposing to continue this policy for the CY 2015 OPPS. We refer readers to section II.H. of this proposed rule for a description and example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in section II.A.2.c. of this proposed rule, for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same proposed FY 2015 pre-reclassified wage index that the IPPS uses to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the original OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Thus, the wage index that applies to a particular acute care short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). As discussed in that final rule with comment period, section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a ''frontier State,'' and amended section 1833(t) of the Act to add new paragraph (19), which requires a ''frontier State'' wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements in § 419.43(c)(2) and (c)(3) of our regulations. For the CY 2015 OPPS, we are proposing to implement this provision in the same manner as we have since CY 2011. That is, frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, rural and imputed floor, and rural floor budget neutrality) is less than 1.00. Similar to our current policy for HOPDs that are affiliated with multi-campus hospital systems, the HOPD would receive a wage index based on the geographic location of the specific inpatient hospital with which it is associated. Therefore, if the associated hospital is located in a frontier State, the wage index adjustment applicable for the hospital would also apply for the affiliated HOPD. We refer readers to the following sections in the FY 2011 through FY 2014 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of frontier States as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: For FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; and for FY 2014, 78 FR 50590 through 50591. We also refer readers to the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28069) for discussion regarding this provision.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2015 IPPS wage indexes continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural and imputed floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). We refer readers to the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28054 through 28084) for a detailed discussion of all proposed changes to the FY 2015 IPPS wage indices. In addition, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65842 through 65844) and subsequent OPPS rules for a detailed discussion of the history of these wage index adjustments as applied under the OPPS.

As discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28054 through 28055), the Office of Management and Budget (OMB) issued revisions to the current labor market area delineations on February 28, 2013, that included a number of significant changes such as new Core Based Statistical Areas (CBSAs), urban counties that become rural, rural counties that become urban, and existing CBSAs that are split apart (OMB Bulletin 13–01). This bulletin can be found at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b13–01.pdf.* As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50586), in order to allow for sufficient time to assess the new revisions and their ramifications, we intended to propose changes to the IPPS wage index based on the newest CBSA delineations in the FY 2015 IPPS/LTCH PPS proposed rule. Similarly, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74951), we stated that we intended to propose changes in the OPPS, which uses the IPPS wage index, based on the new OMB delineations in this CY 2015 OPPS/ASC proposed rule, consistent with any proposals in the FY 2015 IPPS/LTCH PPS proposed rule. We refer readers to proposed changes based on the new OMB delineations in the FY 2015 IPPS/LTCH proposed rule at 79 FR 28054 through 28084.

In this proposed rule, we are proposing to use the proposed FY 2015 hospital IPPS wage index for urban and rural areas as the wage index for the OPPS hospital to determine the wage adjustments for the OPPS payment rate and the copayment standardized amount for CY 2015. (We refer readers to the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28054) and the proposed FY 2015 hospital wage index files posted on the CMS Web site.) We note that the proposed FY 2015 IPPS wage indexes reflect a number of proposed changes as a result of the new OMB delineations as well as a proposed 1-year extension of the imputed rural floor. The CY 2015 OPPS wage index (for hospitals paid under the IPPS and OPPS) would be the final FY 2015 IPPS wage index. Thus, any proposed adjustments, including the adjustments related to the new OMB delineations, that are finalized for the IPPS wage index would be reflected in the OPPS wage index. As stated earlier in this section, we continue to believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. Therefore, we are not proposing to

change our current regulations, which require that we use the FY 2015 IPPS wage indexes for calculating OPPS payments in CY 2015.

Hospitals that are paid under the OPPS but not under the IPPS do not have a hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, we assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. We are proposing to adopt the proposed wage index changes from the FY 2015 IPPS/LTCH PPS proposed rule for these hospitals. The following is a brief summary of the major proposed changes in the FY 2015 IPPS wage indexes and any adjustments that we are proposing to apply to these hospitals under the OPPS for CY 2015. We refer the reader to the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28054 through 28084) for a detailed discussion of the proposed changes to the wage indexes.

For CY 2015, we are proposing to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173)). Applying this adjustment is consistent with our proposed policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment if they are located in a section 505 out-migration county. This is the same proposed out-migration adjustment policy that would apply if the hospital were paid under the IPPS. Table 4J from the FY 2015 IPPS/LTCH PPS proposed rule (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) identifies counties eligible for the out-migration adjustment and IPPS hospitals that would receive the adjustment for FY 2015.

As we have done in prior years, we are including Table 4J from the FY 2015 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2015 OPPS. Addendum L is available via the Internet on the CMS Web site.

In the FY 2015 IPPS/LTCH PPS proposed rule, we proposed to adopt the new OMB labor market area delineations issued by OMB in OMB Bulletin No. 13–01 on February 28, 2013, based on standards published on June 28, 2010 (75 FR 37246 through 37252) and the 2010 Census data to delineate labor market areas for purposes of the IPPS wage index. For IPPS wage index purposes, for hospitals that would be designated as rural under the new OMB labor market area delineations that currently are located in urban CBSAs, we generally proposed to assign them the urban wage index value of the CBSA in which they are physically located for FY 2014 for a period of 3 fiscal years (79 FR 28060 through 28061). To be consistent, we are proposing to apply the same policy to hospitals paid under the OPPS but not under the IPPS so that such hospitals would maintain the wage index of the CBSA in which they are physically located for FY 2014 for the next 3 calendar years. This proposed policy would impact six hospitals for purposes of OPPS payment.

We believe that adopting the new OMB labor market area delineations would create a more accurate wage index system, but we also recognize that implementing the new OMB delineations may cause some short-term instability in hospital payments. Therefore, similar to the policy we adopted in the FY 2005 IPPS final rule (69 FR 49033), in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28062), we proposed a 1-year blended wage index for all hospitals that would experience any decrease in their actual payment wage index exclusively due to the proposed implementation of the new OMB delineations. We proposed that a post-reclassified wage index with the rural and imputed floors applied would be computed based on the hospital's FY 2014 CBSA (that is, using all of its FY 2014 constituent county/ies), and another post-reclassified wage index with the rural and imputed floors applied would be computed based on the hospital's new FY 2015 CBSA (that is, the FY 2015 constituent county/ies). We proposed to compare these two wage indexes. If the proposed FY 2015 wage index with FY 2015 CBSAs would be lower than the proposed FY 2015 wage index with FY 2014 CBSAs, we proposed that a blended wage index would be computed, consisting of 50 percent of each of the two wage indexes added together. We proposed that this blended wage index would be the hospital's wage index for FY 2015. For purposes of the OPPS, we also are proposing to apply this 50-percent transition blend to hospitals paid under the OPPS but not under the IPPS. We believe a 1-year, 50/50 blended wage index would mitigate the short-term instability and negative payment impacts due to the proposed implementation of the new OMB delineations, providing hospitals with a transition period during which they may adjust to their new geographic CBSA. We believe that a longer transition period would reduce the accuracy of the overall labor market area wage index system, and generally would not be warranted for hospitals moving from one urban geographic labor market area to another.

In addition, for the FY 2015 IPPS, we proposed to continue the extension of the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015 (79 FR 28068 through 28069). For purposes of the CY 2015 OPPS, we are also proposing to apply the imputed floor policy to hospitals paid under the OPPS but not under the IPPS.

For CMHCs, we are proposing to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPS hospitals and for the same reasons, we are proposing to apply a 1-year, 50/50 blended wage index to CMHCs that would receive a lower wage index due to the new CBSA delineations. In addition, as with OPPS hospitals and for the same reasons, for CMHCs currently located in urban CBSAs that would be designated as rural under the new OMB labor market area delineations, we are proposing to maintain the urban wage index value of the CBSA in which they are physically located for CY 2014 for the next 3 calendar years. Consistent with our current policy, the wage index that applies to CMHCs includes both the imputed floor adjustment and the rural floor adjustment, but does not include the out-migration adjustment because that adjustment only applies to hospitals.

With the exception of the proposed out-migration wage adjustment table (Addendum L to this proposed rule, which is available via the Internet on the CMS Web site), which includes non-IPPS hospitals paid under the OPPS, we are not reprinting the proposed FY 2015 IPPS wage indexes referenced in this discussion of the wage index. We refer readers to the CMS Web site for the OPPS at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At this link, readers will find a link to the proposed FY 2015 IPPS wage index tables.

D. Proposed Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. MACs cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned above until a hospital's MAC is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, hospitals that are new, have not accepted assignment of an existing hospital's provider agreement, and have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a biased CCR (that is, the CCR falls outside the predetermined ceiling threshold for a valid CCR) or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11). In this proposed rule, we are proposing to update the default ratios for CY 2015 using the most recent cost report data. We discuss our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009.

For CY 2015, we are proposing to continue to use our standard methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that we use to adjust charges to costs on claims data for setting the proposed CY 2015 OPPS relative payment weights. Table 12 below lists the proposed CY 2015 default urban and rural CCRs by State and compares them to last year's default CCRs. These proposed CCRs represent the ratio of total costs to total charges for those cost centers relevant to outpatient services from each hospital's most recently submitted cost report, weighted by Medicare Part B charges. We also are proposing to adjust ratios from submitted cost reports to reflect the final settled status by applying the differential between settled to submitted overall CCRs for the cost centers relevant to outpatient services from the most recent pair of final settled and submitted cost reports. We then are proposing to weight each hospital's CCR by the volume of separately paid line-items on hospital claims corresponding to the year of the majority of cost reports used to calculate the overall CCRs. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66680 through 66682) and prior OPPS rules for a more detailed discussion of our established methodology for calculating the statewide average default CCRs, including the hospitals used in our calculations and our trimming criteria.

For Maryland, we used an overall weighted average CCR for all hospitals in the Nation as a substitute for Maryland CCRs. Few hospitals in Maryland are eligible to receive payment under the OPPS, which limits the data available to calculate an accurate and representative CCR. The weighted CCR is used for Maryland because it takes into account each hospital's volume, rather than treating each hospital equally. We refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65822) for further discussion and the rationale for our longstanding policy of using the national average CCR for Maryland. In general, observed changes in the statewide average default CCRs between CY 2014 and CY 2015 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 12 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2015.

TABLE 12—PROPOSED CY 2015 STATEWIDE AVERAGE CCRS

State	Urban/rural	Proposed CY 2015 default CCR	Previous default CCR (CY 2014 OPPS final rule)
ALASKA	RURAL	0.463	0.473
ALASKA	URBAN	0.301	0.302
ALABAMA	RURAL	0.246	0.229
ALABAMA	URBAN	0.189	0.188
ARKANSAS	RURAL	0.233	0.244
ARKANSAS	URBAN	0.237	0.220
ARIZONA	RURAL	0.232	0.254
ARIZONA	URBAN	0.186	0.182
CALIFORNIA	RURAL	0.192	0.190
CALIFORNIA	URBAN	0.203	0.206
COLORADO	RURAL	0.426	0.393
COLORADO	URBAN	0.223	0.221
CONNECTICUT	RURAL	0.356	0.343
CONNECTICUT	URBAN	0.277	0.276
DISTRICT OF COLUMBIA	URBAN	0.295	0.279
DELAWARE	URBAN	0.314	0.356
FLORIDA	RURAL	0.185	0.160
FLORIDA	URBAN	0.160	0.160
GEORGIA	RURAL	0.254	0.260
GEORGIA	URBAN	0.211	0.205
HAWAII	RURAL	0.341	0.345
HAWAII	URBAN	0.300	0.298
IOWA	RURAL	0.323	0.308
IOWA	URBAN	0.270	0.266
IDAHO	RURAL	0.361	0.359

TABLE 12—PROPOSED CY 2015 STATEWIDE AVERAGE CCRs—Continued

State	Urban/rural	Proposed CY 2015 default CCR	Previous default CCR (CY 2014 OPPS final rule)
IDAHO	URBAN	0.488	0.478
ILLINOIS	RURAL	0.259	0.252
ILLINOIS	URBAN	0.218	0.222
INDIANA	RURAL	0.348	0.326
INDIANA	URBAN	0.284	0.288
KANSAS	RURAL	0.308	0.313
KANSAS	URBAN	0.233	0.239
KENTUCKY	RURAL	0.231	0.221
KENTUCKY	URBAN	0.220	0.225
LOUISIANA	RURAL	0.271	0.257
LOUISIANA	URBAN	0.212	0.222
MARYLAND	RURAL	0.292	0.283
MARYLAND	URBAN	0.249	0.248
MASSACHUSETTS	RURAL	0.300	0.395
MASSACHUSETTS	URBAN	0.330	0.336
MAINE	RURAL	0.434	0.452
MAINE	URBAN	0.426	0.438
MICHIGAN	RURAL	0.339	0.341
MICHIGAN	URBAN	0.322	0.322
MINNESOTA	RURAL	0.469	0.462
MINNESOTA	URBAN	0.357	0.349
MISSOURI	RURAL	0.277	0.263
MISSOURI	URBAN	0.274	0.280
MISSISSIPPI	RURAL	0.237	0.233
MISSISSIPPI	URBAN	0.188	0.200
MONTANA	RURAL	0.520	0.481
MONTANA	URBAN	0.379	0.384
NORTH CAROLINA	RURAL	0.255	0.258
NORTH CAROLINA	URBAN	0.256	0.256
NORTH DAKOTA	RURAL	0.660	0.661
NORTH DAKOTA	URBAN	0.400	0.400
NEBRASKA	RURAL	0.308	0.323
NEBRASKA	URBAN	0.257	0.243
NEW HAMPSHIRE	RURAL	0.272	0.326
NEW HAMPSHIRE	URBAN	0.288	0.287
NEW JERSEY	URBAN	0.207	0.213
NEW MEXICO	RURAL	0.307	0.291
NEW MEXICO	URBAN	0.300	0.304
NEVADA	RURAL	0.244	0.220
NEVADA	URBAN	0.172	0.154
NEW YORK	RURAL	0.332	0.345
NEW YORK	URBAN	0.348	0.351
OHIO	RURAL	0.317	0.327
OHIO	URBAN	0.227	0.232
OKLAHOMA	RURAL	0.281	0.258
OKLAHOMA	URBAN	0.210	0.205
OREGON	RURAL	0.299	0.311
OREGON	URBAN	0.358	0.357
PENNSYLVANIA	RURAL	0.285	0.257
PENNSYLVANIA	URBAN	0.198	0.198
PUERTO RICO	URBAN	0.583	0.614
RHODE ISLAND	URBAN	0.292	0.295
SOUTH CAROLINA	RURAL	0.195	0.190
SOUTH CAROLINA	URBAN	0.199	0.203
SOUTH DAKOTA	RURAL	0.288	0.287
SOUTH DAKOTA	URBAN	0.214	0.219
TENNESSEE	RURAL	0.207	0.207
TENNESSEE	URBAN	0.189	0.190
TEXAS	RURAL	0.247	0.235
TEXAS	URBAN	0.206	0.197
UTAH	RURAL	0.474	0.474
UTAH	URBAN	0.340	0.334
VIRGINIA	RURAL	0.216	0.226
VIRGINIA	URBAN	0.241	0.238
VERMONT	RURAL	0.446	0.456
VERMONT	URBAN	0.401	0.397
WASHINGTON	RURAL	0.300	0.330
WASHINGTON	URBAN	0.365	0.360

TABLE 12—PROPOSED CY 2015 STATEWIDE AVERAGE CCRs—Continued

State	Urban/rural	Proposed CY 2015 default CCR	Previous default CCR (CY 2014 OPPS final rule)
WISCONSIN	RURAL	0.335	0.344
WISCONSIN	URBAN	0.298	0.291
WEST VIRGINIA	RURAL	0.320	0.283
WEST VIRGINIA	URBAN	0.319	0.319
WYOMING	RURAL	0.403	0.400
WYOMING	URBAN	0.262	0.269

E. Proposed Adjustment for Rural SCHs and EACHs Under Section 1833(t)(13)(B) of the Act

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) of the regulations to clarify that EACHs also are eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2014. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2015 OPPS, we are proposing to continue our policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. Proposed OPPS Payment to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), Congress established section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to determine cancer and children's hospitals OPPS payments based on their pre-BBA payment amount (often referred to as ''held harmless'').

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower under the OPPS than the payment they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount,'' including the determination of the base PCR, are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 and Form CMS–2552–10, respectively) as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer and other hospitals. Section 1833(t)(18)(B) of the Act provides that if the Secretary determines that cancer hospitals' costs are greater than other hospitals' costs, the Secretary shall provide an

appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recent submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91. For CY 2014, the target PCR for purposes of the cancer hospital payment adjustment was 0.89.

2. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2015

For CY 2015, we are proposing to continue our policy to provide additional payments to cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals using the most recent submitted or settled cost report data that are available at the time of the development of this proposed rule. To calculate the proposed CY 2015 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of this proposed rule, used to estimate costs for the CY 2015 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2013 claims data that we used to model the impact of the proposed CY 2015 APC relative payment weights (3,881 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2015 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2012 to 2013. We then removed the cost report data of the 47 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 27 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,807 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 89 percent of reasonable cost (weighted average PCR of 0.89). Therefore, we are proposing that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.89 for each cancer hospital.

Table 13 below indicates the estimated percentage increase in OPPS payments to each cancer hospital for CY 2015 due to the cancer hospital payment adjustment policy. The actual amount of the CY 2015 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2015 payments and costs. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 13—ESTIMATED CY 2015 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Estimated percentage increase in OPPS payments for CY 2015
050146	City of Hope Comprehensive Cancer Center	15.5
050660	USC Norris Cancer Hospital	22.0
100079	Sylvester Comprehensive Cancer Center	15.8
100271	H. Lee Moffitt Cancer Center & Research Institute	19.9
220162	Dana-Farber Cancer Institute	47.6
330154	Memorial Sloan-Kettering Cancer Center	45.7
330354	Roswell Park Cancer Institute	16.6
360242	James Cancer Hospital & Solove Research Institute	35.1
390196	Fox Chase Cancer Center	18.5
450076	M.D. Anderson Cancer Center	60.1
500138	Seattle Cancer Care Alliance	53.3

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74958 through 74960), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2014, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $2,900 (the fixed-dollar amount threshold). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the proposed OPPS. Our current estimate of total outlier payments as a percent of total CY 2013 OPPS payment, using available CY 2013 claims and the revised OPPS expenditure estimate for the FY 2015 President's Budget, is approximately 1.2 percent of the total aggregated OPPS payments. Therefore, for CY 2013, we estimate that we paid 0.2 percent above the CY 2013 outlier target of 1.0 percent of total aggregated OPPS payments.

Using CY 2013 claims data and CY 2014 payment rates, we currently estimate that the aggregate outlier payments for CY 2014 will be approximately 0.9 percent of the total CY 2014 OPPS payments. The difference between 0.9 percent and the 1.0 percent target is reflected in the regulatory impact analysis in section XXII. of this proposed rule. We provide estimated CY 2015 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

2. Proposed Outlier Calculation

For CY 2015, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We are proposing that a portion of that 1.0 percent, an amount equal to 0.47 percent of outlier payments (or 0.0047 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.D. of this proposed rule, for CMHCs, we are proposing to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) or APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.D. of this proposed rule.

To ensure that the estimated CY 2015 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $3,100.

We calculated the proposed fixed-dollar threshold of $3,100 using the standard methodology most recently used for CY 2014 (78 FR 74959 through 74960). For purposes of estimating outlier payments for this proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2014 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the Medicare contractors and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2015 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2013 claims using the same inflation factor of 1.1146 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28321). We used an inflation factor of 1.0557 to estimate CY 2014 charges from the CY 2013 charges reported on CY 2013 claims. The methodology for determining this charge inflation factor is discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28321). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we are proposing to apply the same CCR inflation adjustment factor that we are proposing to apply for the FY 2015 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2015 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2015, we are proposing to apply an adjustment factor of 0.9813 to the CCRs that were in the April 2014 OPSF to trend them forward from CY 2014 to CY 2015. The methodology for calculating this proposed adjustment was discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28321).

To model hospital outlier payments for this proposed rule, we applied the overall CCRs from the April 2014 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9813 to approximate CY 2015 CCRs) to charges on CY 2013 claims that were adjusted (using the proposed charge inflation factor of 1.1146 to approximate CY 2015 charges). We simulated aggregated CY 2015 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment

amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2015 OPPS payments. We estimated that a proposed fixed-dollar threshold of $3,100, combined with the proposed multiple threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we are proposing that, if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we are proposing to continue the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

H. Proposed Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR Part 419, Subparts C and D. For this CY 2015 OPPS/ASC proposed rule, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this proposed rule and the relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) was calculated by multiplying the proposed CY 2015 scaled weight for the APC by the proposed CY 2015 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

We demonstrate in the steps below how to determine the APC payments that will be made in a calendar year under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' or ''V,'' (as defined in Addendum D1 to this proposed rule), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements. We note that we are also proposing to create new status indicator ''J1'' to reflect the proposed comprehensive APCs discussed in section II.A.2.e. of this proposed rule. We also note that we are proposing to delete status indicator ''X'' as part of the CY 2015 packaging proposal for ancillary services, discussed in section II.A.3. of this proposed rule.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the proposed national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the proposed national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the proposed reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the proposed full CY 2015 OPPS fee schedule increase factor of 2.1 percent.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 * (\text{national unadjusted payment rate})$.

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that under the proposed CY 2015 OPPS policy for transitioning wage indexes

into the new OMB labor market area delineations, a hold harmless policy for the wage index may apply, as discussed in section II.C. of this proposed rule. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2015 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Pub. L. 98–21. (For further discussion of the proposed changes to the FY 2015 IPPS wage indices, as applied to the CY 2015 OPPS, we refer readers to section II.C. of this proposed rule.) We are proposing to continue to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act of 2010.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this proposed rule (which is available via the Internet on the CMS Web site) contains the qualifying counties and the proposed associated wage index increase developed for the FY 2015 IPPS and listed as Table 4J in the FY 2015 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a *is the labor-related portion of the national unadjusted payment rate (wage adjusted).*

X_a = .60 * (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y *is the nonlabor-related portion of the national unadjusted payment rate.*

Y = .40 * (national unadjusted payment rate).

Adjusted Medicare Payment = $Y + X_a$

Step 6. If a provider is an SCH, set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We have provided examples below of the calculation of both the proposed full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we used a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 0019 (Level I Excision/Biopsy). The proposed CY 2015 full national unadjusted payment rate for APC 0019 is approximately $380.32. The proposed reduced national unadjusted payment rate for APC 0019 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $372.71. This proposed reduced rate is calculated by multiplying the proposed reporting ratio of 0.980 by the full unadjusted payment rate for APC 0019.

The proposed FY 2015 wage index for a provider located in CBSA 35614 in New York is 1.3014. This is based on the proposed 1-year 50/50 transition blend between the wage index under the old CBSA 35644 (1.3147) and the wage index under the new CBSA 35614 (1.2881). The labor-related portion of the proposed full national unadjusted payment is approximately $296.97 (.60 * $380.32 * 1.3014). The labor-related portion of the proposed reduced national unadjusted payment is approximately $291.03 (.60 * $372.71 * 1.3014). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $152.13 (.40 * $380.32). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $149.08 (40 * $372.71). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $449.10 ($296.97 + $152.13). The sum of the proposed reduced national adjusted payment is approximately $440.11 ($291.03 + $149.08).

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in calendar years thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. Proposed OPPS Copayment Policy

For CY 2015, we are proposing to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we are proposing to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2015, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). As discussed in section XII.G. of this proposed rule, for CY 2015, the proposed Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS/ASC final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 0019, approximately $76.07 is 20 percent of the proposed full national unadjusted payment rate of approximately $380.32. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/ national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this proposed rule. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B.*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B.*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the proposed reporting ratio of 0.980.

The proposed unadjusted copayments for services payable under the OPPS that would be effective January 1, 2015, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed full CY 2015 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

In addition, as noted above, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures and medical services;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new CPT and Level II HCPCS codes to interim status indicator (SI) and APC assignments. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and provides payment or more accurate payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. For those items, procedures, or services not paid separately under the hospital OPPS, they are assigned to appropriate status indicators. Section XI. of this proposed rule provides a

discussion of the various status indicators used under the OPPS. Certain payment indicators provide separate payment while others do not.

In Table 14 below, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS. We note that because the payment rates associated with codes that are effective July 1 are not available to us in time for incorporation into the Addenda of this proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2014 OPPS quarterly update CR could not be included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). New and revised codes that were implemented through the April 2014 OPPS quarterly update are included in Addendum B. Nevertheless, we are requesting public comments on the codes included in the July 2014 OPPS quarterly update and including these codes in the preamble of this proposed rule (we refer readers to Table 16 for the July 2014 HCPCS codes).

TABLE 14—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April I, 2014	Level II HCPCS Codes	April 1, 2014	CY 2015 OPPS/ASC proposed rule.	CY 2015 OPPS/ASC final rule with comment period.
July 1, 2014	Level II HCPCS Codes	July 1, 2014	CY 2015 OPPS/ASC proposed rule.	CY 2015 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2014	CY 2015 OPPS/ASC proposed rule.	CY 2015 OPPS/ASC final rule with comment period.
October 1, 2014	Level II HCPCS Codes	October 1, 2014	CY 2015 OPPS/ASC final rule with comment period.	CY 2016 OPPS/ASC final rule with comment period.
January 1, 2015	Level II HCPCS Codes	January 1, 2015	CY 2015 OPPS/ASC final rule with comment period.	CY 2016 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2015	CY 2015 OPPS/ASC final rule with comment period.	CY 2016 OPPS/ASC final rule with comment period.

This process is discussed in detail below. We have separated our discussion into two sections based on whether we are soliciting public comments in this CY 2015 OPPS/ASC proposed rule or whether we will be soliciting public comments in the CY 2015 OPPS/ASC final rule with comment period. We note that we sought public comments in the CY 2014 OPPS/ASC final rule with comment period on the interim APC and status assignments for new CPT and Level II HCPCS codes that were effective January 1, 2014. We also sought public comments in the CY 2014 OPPS/ASC final rule with comment period on the interim APC and status assignments for new Level II HCPCS codes that became effective October 1, 2013. These new and revised codes, with an effective date of October 1, 2013, or January 1, 2014, were flagged with comment indicator ''NI'' (New code, interim APC assignment; comments will be accepted on the interim APC assignment for the new code) in Addendum B to the CY 2014 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and an APC and payment rate, if applicable, and were subject to public comment following publication of the CY 2014 OPPS/ASC final rule with comment period. We will respond to public comments and finalize our interim OPPS treatment of these codes in the CY 2015 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New CY 2014 Level II HCPCS and CPT Codes Effective April 1, 2014 and July 1, 2014 for Which We Are Soliciting Public Comments in This CY 2015 OPPS/ASC Proposed Rule

Through the April 2014 OPPS quarterly update CR (Transmittal 2903, Change Request 8653, dated March 11, 2014), and the July 2014 OPPS quarterly update CR (Transmittal 2971, Change Request 8776, dated May 23, 2014), we recognized several new HCPCS codes for separate payment under the OPPS.

Effective April 1, 2014, we made effective four new Level II HCPCS codes and also assigned them to appropriate interim OPPS status indicators and APCs. Through the April 2014 OPPS quarterly update CR, we allowed separate payment for three of the four new Level II HCPCS codes. Specifically, as displayed in Table 15 below, we provided separate payment for HCPCS codes C9021, C9739, and C9740. HCPCS code Q2052 was assigned to status indicator ''N'' to indicate that this service is packaged under the OPPS.

TABLE 15—NEW LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2014

CY 2014 HCPCS Code	CY 2014 Long descriptor	Proposed CY 2015 status indicator	Proposed CY 2015 APC
C9021*	Injection, obinutuzumab, 10 mg	G	1476
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants	T	0162
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants	T	1564

TABLE 15—NEW LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2014—Continued

CY 2014 HCPCS Code	CY 2014 Long descriptor	Proposed CY 2015 status indicator	Proposed CY 2015 APC
Q2052	Services, supplies and accessories used in the home under the Medicare intravenous immune globulin (ivig) demonstration.	N	N/A

* The proposed payment rate for HCPCS code C9021 is based on published wholesale acquisition cost (PWAC) +6 percent.

In this CY 2015 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments, where applicable, for the Level II HCPCS codes listed in Table 15 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

Effective July 1, 2014, we made effective several new CPT and Level II HCPCS codes and also assigned them to appropriate interim OPPS status indicators and APCs. Through the July 2014 OPPS quarterly update CR, we allowed separate payment under the OPPS for four new Level II HCPCS codes and 17 new Category III CPT codes effective July 1, 2014. Specifically, as displayed in Table 16 below, we allowed separate payment for HCPCS codes C2644, C9022, C9134, and Q9970. We note that HCPCS code Q9970 replaced HCPCS code C9441 (Injection, ferric carboxymaltose, 1 mg), beginning July 1, 2014. HCPCS code C9441 was made effective January 1, 2014, but the code was deleted June 30, 2014, because it was replaced with HCPCS code Q9970. HCPCS code C9441 was granted pass-through payment status when the code was implemented on January 1, 2014. Because HCPCS code Q9970 describes the same drug as HCPCS code C9441, we are proposing to continue the pass-through payment status for HCPCS code Q9970, and assign the HCPCS Q-code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 16. Specifically, we are proposing to assign HCPCS code Q9970 to APC 9441 (Inj, Ferric Carboxymaltose) and status indicator ''G.''

In addition, the HCPCS Workgroup established HCPCS code Q9974, effective July 1, 2014, to replace HCPCS codes J2271 (Injection, morphine sulfate, 100mg) and J2275 (Injection, morphine sulfate (preservative-free sterile solution), per 10 mg). Both of these HCPCS J-codes were assigned to status indicator ''N'' (Packaged Services). As a result of the establishment of new HCPCS code Q9974 as a replacement for HCPCS codes J2271 and J2275, the payment indicator for HCPCS codes J2271 and J2275 was changed to ''E'' (Not Payable by Medicare), effective July 1, 2014. Also, because HCPCS code Q9974 describes the same services that were described by HCPCS codes J2271 and J2275, we are proposing to continue to assign HCPCS code Q9974 to the same status indicator as its predecessor HCPCS J-codes. Specifically, we are proposing to assign HCPCS code Q9974 to status indicator ''N,'' effective July 1, 2014.

We are proposing to assign the Level II HCPCS codes listed in Table 16 to the specified proposed APCs and status indicators set forth in Table 16 of this proposed rule. This table, presented below, includes a complete list of the Level II HCPCS codes that were made effective July 1, 2014. The codes that were made effective July 1, 2014, do not appear in Addendum B to this proposed rule, and as a result, the proposed payment rates along with the proposed status indicators and proposed APC assignments, where applicable, for CY 2015 are provided in Table 16.

TABLE 16—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2014

CY 2014 HCPCS Code	CY 2014 Long descriptor	Proposed CY 2015 status indicator	Proposed CY 2015 APC	Proposed CY 2015 payment rate
C2644	Brachytherapy source, cesium-131 chloride solution, per millicurie	U	2644	$18.97
C9022*	Injection, elosulfase alfa, 1 mg	G	1480	226.42
C9134*	Factor XIII (antihemophilic factor, recombinant), Tretten, per 10 i.u	G	1481	14.10
Q9970**	Injection, ferric carboxymaltose, 1 mg	G	9441	1.06
Q9974***	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg.	N	N/A	N/A

* The proposed payment rates for HCPCS code C9022 and C9134 are based on ASP+6 percent.

** HCPCS code C9441 (Injection, ferric carboxymaltose, 1 mg) was deleted June 30, 2014, and replaced with HCPCS code Q9970, effective July 1, 2014.

*** HCPCS codes J2271 (Injection, morphine sulfate, 100mg) and J2275 (Injection, morphine sulfate (preservative-free sterile solution), per 10 mg) were replaced with HCPCS code Q9974, effective July 1, 2014. Consequently, the payment indicator assignment for HCPCS codes J2271 and J2275 was changed to ''E'' (Not Payable by Medicare), effective July 1, 2014.

For CY 2015, we are proposing to continue our established policy of recognizing Category I CPT vaccine codes for which FDA approval is imminent and Category III CPT codes that the AMA releases in January of each year for implementation in July through the OPPS quarterly update process. Under the OPPS, Category I CPT vaccine codes and Category III CPT codes that are released on the AMA Web site in January are made effective in July of the same year through the July quarterly update CR, consistent with the AMA's implementation date for the codes. For the July 2014 update, there were no new Category I CPT vaccine codes.

Through the July 2014 OPPS quarterly update CR (Transmittal 2971, Change Request 8776, dated May 23, 2014), we assigned interim OPPS status indicators and APCs for 17 of 27 new Category III CPT codes that were made effective July 1, 2014. Specifically, as displayed in Table 17 below, we made interim OPPS status indicators and APC assignments for Category III CPT codes 0347T, 0348T, 0349T, 0350T, 0355T, 0356T, 0358T, 0359T, 0360T, 0362T, 0364T,

0366T, 0368T, 0370T, 0371T, 0372T, and 0373T. Table 17 below lists the Category III CPT codes that were implemented on July 1, 2014, along with the proposed status indicators, proposed APC assignments, and proposed payment rates, where applicable, for CY 2015.

TABLE 17—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2014

CY 2014 CPT Code	CY 2014 Long descriptor	Proposed CY 2015 status indicator	Proposed CY 2015 APC	Proposed CY 2015 payment rate
0347T	Placement of interstitial device(s) in bone for radiostereometric analysis (RSA).	Q2	0420	$125.05
0348T	Radiologic examination, radiostereometric analysis (RSA); spine, (includes, cervical, thoracic and lumbosacral, when performed).	S	0261	95.36
0349T	Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow and wrist, when performed).	S	0261	95.36
0350T	Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies), (includes hip, proximal femur, knee and ankle, when performed).	S	0261	95.36
0351T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real time intraoperative.	N	N/A	N/A
0352T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; interpretation and report, real time or referred.	B	N/A	N/A
0353T	Optical coherence tomography of breast, surgical cavity; real time intraoperative.	N	N/A	N/A
0354T	Optical coherence tomography of breast, surgical cavity; interpretation and report, real time or referred.	B	N/A	N/A
0355T	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report.	T	0142	857.73
0356T	Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each.	Q1	0698	101.41
0358T	Bioelectrical impedance analysis whole body composition assessment, supine position, with interpretation and report.	Q1	0340	61.88
0359T	Behavior identification assessment, by the physician or other qualified health care professional, face-to-face with patient and caregiver(s), includes administration of standardized and non-standardized tests, detailed behavioral history, patient observation and caregiver interview, interpretation of test results, discussion of findings and recommendations with the primary guardian(s)/caregiver(s), and preparation of report.	V	0632	107.98
0360T	Observational behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by one technician; first 30 minutes of technician time, face-to-face with the patient.	V	0632	107.98
0361T	Observational behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by one technician; each additional 30 minutes of technician time, face-to-face with the patient (List separately in addition to code for primary service).	N	N/A	N/A
0362T	Exposure behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by physician or other qualified health care professional with the assistance of one or more technicians; first 30 minutes of technician(s) time, face-to-face with the patient.	V	0632	107.98
0363T	Exposure behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by physician or other qualified health care professional with the assistance of one or more technicians; each additional 30 minutes of technician(s) time, face-to-face with the patient (List separately in addition to code for primary procedure).	N	N/A	N/A
0364T	Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient; first 30 minutes of technician time.	S	0322	92.61
0365T	Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient; each additional 30 minutes of technician time (List separately in addition to code for primary procedure).	N	N/A	N/A
0366T	Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients; first 30 minutes of technician time.	S	0325	65.91
0367T	Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients; each additional 30 minutes of technician time (List separately in addition to code for primary procedure).	N	N/A	N/A
0368T	Adaptive behavior treatment with protocol modification administered by physician or other qualified health care professional with one patient; first 30 minutes of patient face-to-face time.	S	0322	92.61

TABLE 17—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2014—Continued

CY 2014 CPT Code	CY 2014 Long descriptor	Proposed CY 2015 status indicator	Proposed CY 2015 APC	Proposed CY 2015 payment rate
0369T	Adaptive behavior treatment with protocol modification administered by physician or other qualified health care professional with one patient; each additional 30 minutes of patient face-to-face time (List separately in addition to code for primary procedure).	N	N/A	N/A
0370T	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present).	S	0324	130.28
0371T	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present).	S	0324	130.28
0372T	Adaptive behavior treatment social skills group, administered by physician or other qualified health care professional face-to-face with multiple patients.	S	0325	65.91
0373T	Exposure adaptive behavior treatment with protocol modification requiring two or more technicians for severe maladaptive behavior(s); first 60 minutes of technicians' time, face-to-face with patient.	S	0323	117.36
0374T	Exposure adaptive behavior treatment with protocol modification requiring two or more technicians for severe maladaptive behavior(s); each additional 30 minutes of technicians' time face-to-face with patient (List separately in addition to code for primary procedure).	N	N/A	N/A

We are soliciting public comments on the proposed CY 2015 status indicators, APC assignments, and payment rates for the Level II HCPCS codes and the Category III CPT codes that were made effective April 1, 2014, and July 1, 2014. These codes are listed in Tables 15, 16, and 17 of this proposed rule. We also are proposing to finalize the status indicator and APC assignments and payment rates for these codes, if applicable, in the CY 2015 OPPS/ASC final rule with comment period. Because the new Category III CPT and Level II HCPCS codes that become effective for July are not available to us in time for incorporation into the Addenda to this proposed rule, our policy is to include the codes, the proposed status indicators, proposed APCs (where applicable), and proposed payment rates (where applicable) in the preamble of the proposed rule, but not in the Addenda to this proposed rule. These codes are listed in Tables 16 and 17, respectively, of this proposed rule. We are proposing to incorporate these codes into Addendum B to the CY 2015 OPPS/ASC final rule with comment period, which is consistent with our annual OPPS update policy. The Level II HCPCS codes implemented or modified through the April 2014 OPPS update CR and displayed in Table 15 are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site), where the proposed CY 2015 payment rates for these codes are also shown.

2. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2014 and New CPT and Level II HCPCS Codes That Will Be Effective January 1, 2015 for Which We Will Be Soliciting Public Comments in the CY 2015 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the OPPS for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January OPPS quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period updating the OPPS for the following calendar year. For CY 2015, these codes will be flagged with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. In addition, the CPT and Level II HCPCS codes that will be effective January 1, 2015, will be flagged with comment indicator ''NI'' in Addendum B to the CY 2015 OPPS/ASC final rule with comment period. Specifically, the status indicator and the APC assignment and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the final rule with comment period, and we respond to these public comments in the OPPS/ASC final rule with comment period for the next calendar year's OPPS/ASC update. We are proposing to continue this process for CY 2015. Specifically, for CY 2015, we are proposing to include in Addendum B to the CY 2015 OPPS/ASC final rule with comment period the following new HCPCS codes:

- New Level II HCPCS codes effective October 1, 2014 that would be incorporated in the October 2014 OPPS quarterly update CR;
- New Category I and III CPT codes effective January 1, 2015 that would be incorporated in the January 2015 OPPS quarterly update CR; and
- New Level II HCPCS codes effective January 1, 2015 that would be incorporated in the January 2015 OPPS quarterly update CR.

As stated above, the October 1, 2014 and January 1, 2015 codes would be flagged with comment indicator ''NI'' in Addendum B to the CY 2015 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2015. We will be inviting public comments on the proposed status indicator and APC assignments and payment rates for these codes, if applicable, that would be finalized in the CY 2016 OPPS/ASC final rule with comment period.

3. Proposed Process for Soliciting Public Comments for New and Revised CPT Codes That Would Be Released by AMA Before the January 1 Effective Date

We generally incorporate the new CPT codes that are effective January 1 in the OPPS/ASC final rule with comment

period. We establish interim APC and status indicator assignments for the coming year, and request comments on the interim assignments. Similarly, in the OPPS/ASC final rule with comment period, we establish interim APC and status indicator assignments for existing CPT codes that have substantial revision to their code descriptors, which may include grammatical changes to the code descriptors that necessitate a change in the current APC assignments. In both cases, we assign these new and revised codes to OPPS comment indicator ''NI'' (New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.) in the OPPS/ASC final rule with comment period. We respond to comments and finalize the APC and status indicator assignments for these CPT codes in the following year's OPPS/ASC final rule with comment period.

a. Current Process for Accepting Comments on New and Revised CPT Codes That Are Effective January 1

Currently, under the hospital OPPS, new CPT codes that are effective January 1 are flagged with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to indicate that the codes are new for the calendar year and have been assigned interim APCs and status indicators, and that we are accepting public comments on the treatment of these new codes. We address public comments in the next year's OPPS/ASC final rule with comment period and finalize the APC and status indicator assignments for the codes. For example, the new CPT codes that were effective January 1, 2013, were assigned to comment indicator ''NI'' in Addendum B to the CY 2013 OPPS/ASC final rule with comment period. We responded to public comments received on the CY 2013 OPPS/ASC final rule with comment period and finalized the APC and status indicator assignments for these codes in the CY 2014 OPPS/ASC final rule with comment period; and we included the final APC and status indicator assignments in Addendum B to that rule.

Similarly, existing CPT codes with substantial revisions to the code descriptors are flagged with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to indicate that these codes are assigned interim APC and status indicators on which we are accepting public comments. Public comments regarding these revised CPT codes are also addressed, and APC and status indicator assignments finalized, in the next year's OPPS/ASC final rule with comment period.

Several stakeholders, including consultants, device manufacturers, drug manufacturers, as well as specialty societies and hospitals, have expressed concern with the process we use to recognize new and revised CPT codes. They believe that CMS should publish proposed APCs and status indicators for the new and revised CPT codes that will be effective January 1 in the OPPS/ASC proposed rule, and request public comments prior to finalizing them for the January 1 implementation date. Further, the stakeholders believe that seeking public input on the APC and status indicator assignments for these new and revised codes would assist CMS in assigning the CPT codes to appropriate APCs. We have been informed of similar concerns regarding our process for assigning interim payment values for revalued, and new and revised codes, under the Medicare Physician Fee Schedule (MPFS), and include proposed policies to address those concerns in the CY 2015 MPFS proposed rule.

Like the MPFS, the OPPS and the ASC payment system rely principally upon the Current Procedural Terminology (CPT®) coding system maintained by the AMA for billing. CPT® is the standard code set adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for outpatient services. The AMA CPT Editorial Panel's coding cycle occurs concurrently with our calendar year rulemaking cycle for the OPPS and the ASC payment system. The OPPS/ASC proposed rules are published prior to the publication of the CPT codes that are generally made public in the Fall, with a January 1 effective date, and we are currently unable to include these codes in the OPPS/ASC proposed rules. Consequently, we establish interim APC and status indicator assignments for new and revised CPT codes that have an effective date of January 1, and we make payment based on those interim designations for one year.

b. Proposal To Modify the Current Process for Accepting Comments on New and Revised CPT Codes That Are Effective January 1

In this CY 2015 OPPS/ASC proposed rule, we are proposing to make changes in the process we use to establish APC assignments and status indicators for new and revised codes. We are proposing to make similar revisions under the MPFS to our current process for establishing values (work and malpractice relative value units and practice expense inputs) for new and revised CPT codes that take effect each January 1.

For instance, we are proposing that, for new and revised CPT codes that we receive from the AMA CPT Editorial Panel too late for inclusion in the proposed rule for a year, we would delay adoption of the new and revised codes for that year, and instead, adopt coding policies and payment rates that conform, to the extent possible, to the policies and payment rates in place for the previous year. We are proposing to adopt these conforming coding and payment policies on an interim basis pending the result of our specific proposals for status indicator and APC assignments for these new and revised codes through notice and comment rulemaking in the OPPS/ASC proposed rule for the following year. Because the changes in CPT codes are effective on January 1 of each year, and CMS would not have established status indicator or APC assignments for these new or revised codes, it would not be practicable for Medicare to use those CPT codes. In this circumstance, we are proposing to create HCPCS G-codes to describe the predecessor codes for any codes that were revised or deleted as part of the annual CPT coding changes. However, if certain CPT codes are revised in a manner that would not affect the cost of inputs (for example, a grammatical change to CPT code descriptors), we would use these revised codes and continue to assign those codes to their current APC. For example, under this proposed process, if a single CPT code was separated into two codes and we did not receive those codes until May 2015, we would assign each of those codes to status indicator ''B'' in the final rule with comment period, to indicate that an alternate code is recognized under the OPPS. Hospitals could not use those two new CPT codes to bill Medicare for outpatient services the first year after the effective date of the codes. Instead, we would create a HCPCS G-code with the same description as the single predecessor CPT code, and continue to use the same APC and status indicator assignment for that code during the year. We would propose status indicator and APC assignments for the two new CPT codes during rulemaking in CY 2016 for payment beginning in CY 2017.

For new codes that describe wholly new services, as opposed to new or revised codes that describe services for which APC and status indicator assignments are already established, we

would make every effort to work with the AMA CPT Editorial Panel to ensure that we received the codes in time to propose payment rates in the proposed rule. However, if we do not receive the code for a wholly new service in time to include proposed APC and status indicator assignments in the proposed rule for a year, we would need to establish interim APC and status indicator assignments for the initial year. We are proposing to establish the initial APC and status indicator assignments for new services as interim final assignments, and to follow our current process to solicit and respond to public comments and finalize the APC and status indicator assignments in the subsequent year.

We recognize that the use of HCPCS G-codes may place an administrative burden on those providers that bill for services under the OPPS and the ASC payment system. We are hopeful that the AMA CPT Editorial Panel ultimately will be able to adjust its timelines and processes so that most, if not all, of the annual coding changes can be addressed in the proposed rule. We are proposing to implement the revised CMS process for establishing APC and status indicator assignments for new and revised codes for CY 2016. However, we will consider alternative implementation dates to allow time for the AMA CPT Editorial Panel to adjust its schedule in order to avoid the necessity to use numerous HCPCS G-codes.

In summary, in conjunction with the proposals presented in the CY 2015 MPFS proposed rule to revise the process used to address new, revised, and potentially misvalued codes under the MPFS, we are proposing to include in the OPPS/ASC proposed rule for a year proposed APC and status indicator assignments for the new and revised CPT codes that are effective January 1. We would follow this revised process except in the case of a code that describes a wholly new service (such as a new technology or new surgical procedure) that has not previously been addressed under the OPPS. For codes that describe new services, we would establish interim APC and status indicator assignments in the OPPS/ASC final rules with comment period, as is our current process. The proposed revised process would eliminate our current practice of assigning interim APC and status indicators for the new and revised CPT codes that take effect on January 1 each year. Instead, when we do not receive new and revised codes early enough in our ratesetting process to propose APC and status indicator assignments in the OPPS/ASC proposed rule for a year, we would create and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we could include proposed assignments in the following year's proposed rule. After proposing APC and status indicator assignments for the new and revised codes in a proposed rule, we would accept comments on the proposed assignments, and respond to the comments and assign the final APC and status indicator assignments in the OPPS/ASC final rules with comment period. We are inviting public comments on this proposal. We are specifically interested in receiving public comments on the following topics:

- Is this proposal preferable to the present process? Are there other alternatives?
- If we were to implement this proposal, is it better to move forward with the changes or is more time needed to make the transition and, therefore, implementation should be delayed beyond CY 2016?
- Are there alternatives other than the use of HCPCS G-codes that would allow us to address the annual CPT code changes through notice and comment rather than interim final rulemaking?
- Is the process we have proposed for wholly new services appropriate? How should we define new services?
- Are there any classes of services, other than new services, that should remain on an interim final schedule?

B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in § 419.31 of the regulations. We use Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to the items and services listed in 419.2(b) of the regulations. Further discussion of packaged services is included in section II.A.3. of this proposed rule.

In CY 2008, we implemented composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service (72 FR 66650 through 66652). For CY 2014, we provided composite APC payments for nine categories of services:

- Mental Health Services Composite (APC 0034).
- Cardiac Electrophysiologic Evaluation and Ablation Composite (APC 8000).
- Low Dose Rate (LDR) Prostate Brachytherapy Composite (APC 8001).
- Ultrasound Composite (APC 8004).
- CT and CTA without Contrast Composite (APC 8005).
- CT and CTA with Contrast Composite (APC 8006).
- MRI and MRA without Contrast Composite (APC 8007).
- MRI and MRA with Contrast Composite (APC 8008).
- Extended Assessment & Management Composite (APC 8009).

A further discussion of composite APCs is included in section II.A.2.f. of this proposed rule.

Under the OPPS, we generally pay for hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. Each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 0634 (Hospital Clinic Visits). The APC relative payment weights are scaled to APC 0634 because it is the hospital clinic visit APC and

clinic visits are among the most frequently furnished services in the hospital outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review, on a recurring basis occurring no less than annually, and revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights (the Panel recommendations for specific services for the CY 2015 OPPS and our responses to them are discussed in the relevant specific sections throughout this proposed rule).

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act).

2. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the cost of the highest cost item or service within an APC group is more than 2 times greater than the cost of the lowest cost item or service within that same group. In making this determination, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims (or less than 1,000 claims) is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost. In this proposed rule, for CY 2015, we are proposing to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services.

We have identified the APCs with 2 times rule violations for CY 2015. Therefore, we are proposing changes to the procedure codes assigned to these APCs assignments in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of the CY 2015 OPPS/ASC proposed rule. Rather, it is published and made available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* In these cases, to eliminate a 2 times rule violation or to improve clinical and resource homogeneity, we are proposing to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2015 included in this proposed rule are related to changes in costs of services that were observed in the CY 2013 claims data newly available for CY 2015 ratesetting. We also are proposing changes to the status indicators for some procedure codes that are not specifically and separately discussed in this proposed rule. In these cases, we are proposing to change the status indicators for these procedure codes because we believe that another status indicator would more accurately describe their payment status from an OPPS perspective based on the policies that we are proposing for CY 2015. In addition, we are proposing to rename existing APCs or create new clinical APCs to complement the proposed procedure code reassignments. Addendum B to this CY 2015 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we are proposing a change to the APC assignment or status indicator, or both, that were initially assigned in the April 2014 Addendum B Update (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*).

3. Proposed Exceptions to the 2 Times Rule

As discussed earlier, we may make exceptions to the 2 times rule limit on the variation of costs within each APC group in unusual cases such as low-volume items and services. Taking into account the APC changes that we are proposing for CY 2015, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2013 claims data available for this proposed rule, we found 9 APCs with 2 times rule violations. We applied the criteria as described above to identify the APCs that we are proposing to make exceptions for under the 2 times rule for CY 2015, and identified 9 APCs that met the criteria for an exception to the 2 times rule based on the CY 2013 claims data available for this proposed rule. We have not included in this determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 0375 (Ancillary Outpatient Services when Patient Expires), which has an APC cost set based on multiple procedure claims. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent APCs, with 2 times rule violations. For a detailed discussion of these criteria, we refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18457 and 18458).

We note that, for cases in which a recommendation by the Panel appears to result in or allow a violation of the 2 times rule, we generally accept the Panel's recommendation because those recommendations are based on explicit consideration (that is, a review of the latest OPPS claims data and group discussion of the issue) of resource use, clinical homogeneity, site of service,

and the quality of the claims data used to determine the APC payment rates.

Table 18 of this proposed rule lists the 9 APCs that we are proposing to make exceptions for under the 2 times rule for CY 2015 based on the criteria cited above and claims data processed from January 1, 2013, through December 31, 2013. For the final rule with comment period, we intend to use claims data for dates of service between January 1, 2013, and December 31, 2013, that were processed on or before June 30, 2014, and updated CCRs, if available.

TABLE 18—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2015

Proposed CY 2015 APC	Proposed CY 2015 APC title
0012	Level I Debridement & Destruction.
0015	Level II Debridement & Destruction.
0057	Bunion Procedures.
0066	Level V Radiation Therapy.
0330	Dental Procedures.
0433	Level II Pathology.
0450	Level I Minor Procedures.
0634	Hospital Clinic Visits.
0661	Level III Pathology.

The proposed costs for hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

C. Proposed OPPS APC-Specific Policies

Section 1833(t)(9) of the Act requires that we annually review and revise, if necessary, the APCs and the procedure code assignments. Therefore, every year we evaluate and revise, if necessary, the APC assignments for procedure codes based on evaluation of the latest hospital outpatient claims data. Although we do not discuss every APC revision and procedure code reassignment in the proposed and final rules with comment period, these revisions and/or reassignments are listed in the OPPS Addendum B to the proposed and final rules with comment period. Specifically, procedure codes proposed for reassignment to new APCs and/or status indicators are assigned to comment indicator ''CH'' (Active HCPCS code in current year and next calendar year, status indicator and/or APC assignment has changed) in the OPPS Addendum B to the proposed and final rules with comment period.

In accordance with section 1833(t)(2) of the Act, we annually review all APC assignments to determine if any 2 times rule violations exist. That is, we review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the cost of the highest cost item or service within an APC group is more than 2 times the cost of the lowest cost item or service within that same group. In making this determination, we consider only those HCPCS codes that are significant based on the number of claims.

As stated in section III.B. of this proposed rule, for purposes of identifying significant procedure codes for examination of possible 2 times rule violations within an APC, we consider procedure codes that have either more than 1,000 single major claims, or (if less than 1,000 single major claims) procedure codes that have more than 99 single major claims and contribute at least 2 percent of the single major claims. This longstanding criterion to determine when a procedure code is significant for purposes of evaluation of a possible 2 times rule violation was established because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost.

1. Ophthalmic Procedures and Services

For the CY 2015 OPPS update, based on our evaluation of the latest hospital outpatient claims data available for this proposed rule, we are proposing to restructure all of the ophthalmic-related APCs to better reflect the costs and clinical characteristics of the procedures within each APC. This proposed restructuring results in the use of 13 APCs for the ophthalmology-related procedures for the CY 2015 OPPS update, as compared to the 24 APCs used for the CY 2014 OPPS update. We believe this major restructuring and consolidation of APCs more appropriately categorizes all of the ophthalmology-related procedures and services within an APC group, such that the services within each newly-configured APC are more comparable clinically and with respect to resource use. Tables 19 and 20 below show the current CY 2014 and proposed CY 2015 ophthalmology-related APCs. Specifically, Table 19 shows the ophthalmology-related APCs and status indicator assignments used for CY 2014, while Table 20 shows the proposed ophthalmology-related APCs and their status indicator assignments for CY 2015. The proposed payment rates for the ophthalmology-related procedure codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 19—CY 2014 OPHTHALMOLOGY-RELATED APCS

CY 2014 APC	APC Title description	CY 2014 status indicator
0035	Vascular Puncture and Minor Diagnostic Procedures	X
0230	Level I Eye Tests & Treatments	S
0231	Level III Eye Tests & Treatments	S
0232	Level I Anterior Segment Eye Procedures	T
0233	Level III Anterior Segment Eye Procedures	T
0234	Level IV Anterior Segment Eye Procedures	T
0235	Level I Posterior Segment Eye Procedures	T
0237	Level II Posterior Segment Eye Procedures	T
0238	Level I Repair and Plastic Eye Procedures	T
0239	Level II Repair and Plastic Eye Procedures	T
0240	Level III Repair and Plastic Eye Procedures	T
0241	Level IV Repair and Plastic Eye Procedures	T
0242	Level V Repair and Plastic Eye Procedures	T
0243	Strabismus/Muscle Procedures	T
0244	Corneal and Amniotic Membrane Transplant	T
0246	Cataract Procedures with IOL Insert	T

TABLE 19—CY 2014 OPHTHALMOLOGY-RELATED APCS—Continued

CY 2014 APC	APC Title description	CY 2014 status indicator
0247	Laser Eye Procedures	T
0249	Cataract Procedures without IOL Insert	T
0255	Level II Anterior Segment Eye Procedures	T
0293	Level VI Anterior Segment Eye Procedures	T
0672	Level III Posterior Segment Eye Procedures	T
0673	Level V Anterior Segment Eye Procedures	T
0698	Level II Eye Tests & Treatments	S
0699	Level IV Eye Tests & Treatments	T

TABLE 20—PROPOSED CY 2015 OPHTHALMOLOGY-RELATED APCS

Proposed CY 2015 APC	APC Title description	Proposed CY 2015 status indicator
0230	Level I Eye Tests & Treatments	S
0231	Level III Eye Tests & Treatments	S
0233	Level II Intraocular Procedures	T
0238	Level I Extraocular, Repair, and Plastic Eye Procedures	T
0239	Level II Extraocular, Repair, and Plastic Eye Procedures	T
0240	Level III Extraocular, Repair, and Plastic Eye Procedures	T
0242	Level IV Extraocular, Repair, and Plastic Eye Procedures	T
0247	Laser Eye Procedures	T
0255	Level I Intraocular Procedures	T
0293	Level IV Intraocular Procedures	J1
0351	Level V Intraocular Procedures	J1
0673	Level III Intraocular Procedures	T
0698	Level II Eye Tests & Treatments	S

We intend to propose similar major restructures of the APC and procedure code assignments for other clinical areas in future rulemakings. We are inviting public comments on this proposal.

2. Female Reproductive Procedures (APCs 0188, 0189, 0192, 0193, and 0202)

At the Panel's March 10, 2014 meeting, a presenter expressed concern regarding the reassignment of the female reproductive procedures within existing APCs 0192 (Level IV Female Reproductive Procedures), 0193 (Level V Female Reproductive Procedures), and 0195 (Level VI Female Reproductive Procedures) that were made effective for the CY 2014 OPPS update, and stated that the changes would compromise beneficiary access to pelvic floor repair procedures. The commenter urged the Panel to request that CMS revisit its packaging policy for APCs 0193 and 0195 and allow stakeholders the opportunity to work with CMS to appropriately reassign these procedures in a manner that better accounts for clinical complexity. In addition, this presenter requested that CMS postpone converting existing APC 0202 (Level VII Female Reproductive Procedures) into a comprehensive APC to allow for further study of the complexity of pelvic floor repair procedures. After review of the information provided by the presenter and examination of the latest hospital outpatient claims data available for this proposed rule, the Panel made no recommendation for any of the female reproductive APCs.

For the CY 2014 OPPS update, we made several APC changes, which included changes to the female reproductive APCs 0192, 0193, and 0195. These changes were listed in Addendum B to the CY 2014 OPPS/ASC proposed rule. Of these three APCs, only APC 0193 showed a 2 times rule violation. We note that, under the OPPS, we may make exceptions to the 2 times rule based on the variation of costs within each APC group in unusual cases such as low-volume items and services. In the case of APC 0193, we believed that it was necessary to make an exception to the 2 times rule for APC 0193 for the CY 2014 OPPS update because this APC sufficiently reflected the clinical and resource coherence of the Level V female reproductive procedures.

For the CY 2015 OPPS update, based on our review of the latest hospital outpatient claims data available for this proposed rule, there are no 2 times rule violations for any of the female reproductive APCs. In addition, based on our evaluation of the latest hospital outpatient claims data, we are proposing to restructure the female reproductive APCs to more appropriately reflect the resource and clinical characteristics of the procedures within each APC. This proposed restructuring results in the use of five APCs for the CY 2015 OPPS update, as compared to the seven APCs used for the CY 2014 OPPS update. We believe that this proposed five-level APC structure will provide more accurate payments for the female reproductive procedures furnished to Medicare beneficiaries.

In summary, we are proposing to restructure the female reproductive APCs based on a review of our latest hospital outpatient claims data available for this proposed rule, which results in the use of five levels of APCs for CY 2015, as compared to the seven APCs used in CY 2014. Tables 21 and 22 below show the current CY 2014 and proposed CY 2015 female reproductive APCs. Specifically, Table 21 shows the female reproductive APCs, APC titles, and their status indicator assignments for CY 2014, while Table 22 shows the proposed female reproductive APCs, APC titles, and their status indicator assignments for CY 2015. The proposed payment rates for the female

reproductive procedure codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). We note that one of the five levels of the female reproductive APCs, APC 0202, is a comprehensive APC. We refer readers to section II.A.2.e. of this proposed rule for further discussion of our comprehensive APC policy.

TABLE 21—CY 2014 FEMALE REPRODUCTIVE APCS

CY 2014 APC	APC Title description	CY 2014 Status indicator
0188	Level II Female Reproductive Proc	T
0189	Level III Female Reproductive Proc	T
0191	Level I Female Reproductive Proc	T
0192	Level IV Female Reproductive Proc	T
0193	Level V Female Reproductive Proc	T
0195	Level VI Female Reproductive Procedures	T
0202	Level VII Female Reproductive Procedures	T

TABLE 22—PROPOSED CY 2015 FEMALE REPRODUCTIVE APCS

Proposed CY 2015 APC	APC Title description	Proposed CY 2015 status indicator
0188	Level I Female Reproductive Procedures	T
0189	Level II Female Reproductive Procedures	T
0192	Level III Female Reproductive Procedures	T
0193	Level IV Female Reproductive Procedures	T
0202	Level V Female Reproductive Procedures	J1

3. Image-Guided Breast Biopsy Procedures (APC 0005)

For the CY 2014 OPPS update, the AMA CPT Editorial Panel deleted the image-guided breast biopsy CPT codes 19102 and 19103 and replaced these specific procedure codes with six new CPT codes that ''bundled'' associated imaging services, effective January 1, 2014. As shown in Table 23 below, CPT codes 19102 and 19103 described percutaneous image-guided breast biopsies using specific devices. Specifically, CPT code 19102 described a breast biopsy performed using a core needle, and CPT code 19103 described a breast biopsy performed using either a vacuum-assisted or rotating device.

In CY 2013, to appropriately report the procedure code for an image-guided breast biopsy using a core needle, an automated vacuum-assisted device, or a rotating biopsy device, multiple procedure codes were required to identify the service performed. That is, a procedure code describing the device-related breast biopsy procedure was required to be reported in combination with the procedure code describing the localization device used during the procedures, as well as the specific image-guidance procedure codes describing the imaging service. Table 23 below shows how image-guided breast biopsy procedures were reported prior to CY 2014. Table 23 also shows the CY 2013 OPPS status indicators, APC assignments, and payment rates for the breast biopsy procedure codes, the localization devices used during the procedures and the specific image-guidance procedure codes describing the imaging service.

TABLE 23—HOW IMAGE-GUIDED BREAST BIOPSY PROCEDURES WERE REPORTED IN CY 2013

CY 2013 CPT code	Long descriptor	CY 2013 SI	CY 2013 APC	CY 2013 Payment
Device-Related Breast Biopsy CPT Codes				
19102	Biopsy of breast; percutaneous, needle core, using imaging guidance	T	0005	$625.24
19103	Biopsy of breast; percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance.	T	0037	1,118.54
Localization Device CPT Codes Reported with CPT Codes 19102 and 19103				
19290	Preoperative placement of needle localization wire, breast	Q1	0340	49.64
19291	Preoperative placement of needle localization wire, breast; each additional lesion (List separately in addition to code for primary procedure).	N	N/A	N/A
19295	Image guided placement, metallic localization clip, percutaneous, during breast biopsy/aspiration (List separately in addition to code for primary procedure).	Q1	0340	49.64
Image Guidance CPT Codes Reported with CPT Codes 19102 and 19103				
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation.	N	N/A	N/A

TABLE 23—HOW IMAGE-GUIDED BREAST BIOPSY PROCEDURES WERE REPORTED IN CY 2013—Continued

CY 2013 CPT code	Long descriptor	CY 2013 SI	CY 2013 APC	CY 2013 Payment
77021	Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation.	N	N/A	N/A
77031	Stereotactic localization guidance for breast biopsy or needle placement (eg, for wire localization or for injection), each lesion, radiological supervision and interpretation.	N	N/A	N/A
77032	Mammographic guidance for needle placement, breast (eg, for wire localization or for injection), each lesion, radiological supervision and interpretation.	N	N/A	N/A

For the CY 2014 OPPS update, the AMA CPT Editorial Panel grouped these multiple procedures that describe these imaging services into single comprehensive service codes; specifically, CPT codes 19081, 19082, 19083, 19084, 19085, and 19086. Table 24 below shows the six new CPT codes that replaced obsolete CPT codes 19102 and 19103. These comprehensive breast biopsy procedure codes are differentiated based on the use of specific imaging-guidance devices—specifically imaging services performed using stereotactic guidance, ultrasound guidance, or magnetic-resonance guidance.

As has been our practice since the implementation of the OPPS in 2000, we review all new procedure codes before assigning the codes to an APC. Based on our understanding of the resources required to furnish the service as defined in the code descriptor, as well as input from our medical advisors, we assigned replacement CPT codes 19081, 19083, and 19085 to APC 0005 (Level II Needle Biopsy/Aspiration Except Bone Marrow) for the CY 2014 OPPS update. We note that, for the CY 2014 OPPS update, we finalized our policy to package all add-on codes (except those for drug administration), effective January 1, 2014. Consequently, payment for replacement CPT codes 19082, 19084, and 19086, which describe add-on procedures, were packaged for CY 2014.

In addition, consistent with our longstanding policy for the treatment of new codes, we assigned these new replacement CPT codes to interim APCs for CY 2014. Specifically, we assigned new CPT codes 19081, 19083, and 19085 to comment indicator ''NI'' in Addendum B to the CY 2014 OPPS/ASC final rule with comment period (which is available via the CMS Web site) to indicate that the codes were new with an interim APC assignment that was subject to public comment.

At the Panel's March 10, 2014 meeting, a presenter requested the reassignment of comprehensive CPT codes 19081, 19083, and 19085 from APC 0005 (Level II Needle Biopsy/Aspiration Except Bone Marrow), which has a CY 2014 OPPS payment rate of $702.08, to APC 0037 (Level IV Needle Biopsy/Aspiration Except Bone Marrow), which has a CY 2014 OPPS payment rate of $1,223.25. The presenter indicated that it is inappropriate to combine all of the new replacement CPT codes into one APC without regard for the imaging modality or device used to perform the procedure. This same presenter also requested that CMS maintain the historic assignment of the predecessor CPT codes cost data.

The Panel recommended that CMS reassign the APC assignments for the new replacement CPT codes. Specifically, the Panel recommended the reassignment of CPT codes 19081, 19083, and 19085 from APC 0005 to APC 0037.

In light of the public presentation and the Panel's recommendation, and our longstanding policy of reviewing, on an annual basis, the APC assignments for all services and items paid under the OPPS, we evaluated the geometric mean costs associated with all of the procedures assigned to the existing four needle biopsy APCs, specifically, APCs 0004 (Level I Needle Biopsy/Aspiration Except Bone Marrow), 0005, 0685 (Level III Needle Biopsy/Aspiration Except Bone Marrow), and 0037. For this CY 2015 OPPS/ASC proposed rule, based on our review of the latest hospital outpatient claims data available for the proposed rule, we are proposing to reassign all of the procedures assigned to APCs 0685 and 0037 to either APC 0004 or APC 0005 based on clinical and resource homogeneity. With this proposed revision, there would be no procedures assigned to APCs 0685 or 0037. Therefore, we are proposing to delete APCs 0685 and 0037 for CY 2015. Consequently, for the CY 2015 OPPS update, we are proposing to use only two needle biopsy APCs, specifically, APCs 0004 and 0005. The proposed reassignment of the procedures assigned to APCs 0685 and 0037 would result in increased payment rates for both APCs 0004 and 0005. For CY 2015, the proposed payment rate for APC 0004 is approximately $494, which is 20 percent higher than the CY 2014 OPPS payment rate of approximately $411. Similarly, the proposed payment rate for APC 0005 is approximately $ 1,062, which is 51 percent higher than the CY 2014 OPPS payment rate of approximately $702. With this proposed reassignment, CPT codes 19081, 19083, and 19085 will continue to be assigned to APC 0005.

In summary, we are proposing to continue to assign CPT codes 19081, 19083, and 19085 to APC 0005, which has a proposed payment rate of approximately $1,062. In addition, we are proposing to continue to package payment for add-on CPT codes 19082, 19084, and 19086 under the OPPS for CY 2015, consistent with our packaging policy for add-on codes that was implemented on January 1, 2014. Because we are proposing to delete APC 0037 as obsolete for CY 2015, we believe that the proposed increased payment rate for APC 0005 is consistent with the Panel's recommendation to reassign CPT codes 19081, 19083, and 19085 to an appropriate APC based on resource utilization and clinical coherence. Table 24 below shows the proposed status indicators, APC assignments, and payment rates for the image-guided breast biopsy CPT codes 19081 through 19086 for the CY 2015 OPPS update.

TABLE 24—PROPOSED APCS TO WHICH IMAGE-GUIDED BREAST BIOPSY PROCEDURE CODES WOULD BE ASSIGNED FOR CY 2015

CY 2014 CPT code	Long descriptor	CY 2014 SI	CY 2014 APC	CY 2014 payment rate	Proposed CY 2015 SI	Proposed CY 2015 APC	Proposed CY 2015 payment rate
19081	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance.	T	0005	$702.08	T	0005	$1,062.28
19082	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including stereotactic guidance (List separately in addition to code for primary procedure).	N	N/A	N/A	N	N/A	N/A
19083	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including ultrasound guidance.	T	0005	702.08	T	0005	1,062.28
19084	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including ultrasound guidance (List separately in addition to code for primary procedure).	N	N/A	N/A	N	N/A	N/A
19085	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance.	T	0005	702.08	T	0005	1,062.28
19086	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure).	N	N/A	N/A	N	N/A	N/A

4. Image-Guided Abscess Drainage Procedures (APCs 0005 and 0007)

For the CY 2014 OPPS update, the AMA CPT Editorial Panel established CPT code 10030 to report the bundled service of image-guided fluid collection drainage by catheter for percutaneous soft tissue, and CPT code 49407 to report the bundled service of image-guided fluid collection drainage by catheter for peritoneal, retroperitoneal, transvaginal or transrectal collections, effective January 1, 2014. As shown in Table 25, which shows the long descriptors for CPT codes 10030 and 49407, and as listed in Addendum B to the CY 2014 OPPS/ASC final rule with comment period, we assigned CPT code 10030 to APC 0006 (Level I Incision & Drainage), with a payment rate of $159.66, and assigned CPT code 49407 to APC 0685 (Level III Needle Biopsy/Aspiration Except Bone Marrow), with a payment rate of $757.76. In addition, as listed in Addendum B to the CY 2014 OPPS/ASC final rule with comment period, both procedure codes were assigned to comment indicator ''NI'' to indicate that the codes were new codes and assigned interim APC and status indicator assignments that were subject to comment.

At the Panel's March 10, 2014 meeting, a presenter requested the reassignment of both CPT codes 10030 and 49407 to APC 0037 (Level IV Needle Biopsy/Aspiration Except Bone Marrow), which has a CY 2014 OPPS payment rate of $1,223.25 and where similar procedures are assigned. Specifically, the presenter indicated that all the image-guided fluid collection drainage procedures should be treated as one clinically cohesive group and should be assigned to APC 0037.

Based on the request, the Panel agreed with the presenter and recommended that CMS reassign CPT code 49407 to APC 0037. However, the Panel did not agree with the reassignment of CPT code 10030 to APC 0037. Rather, the Panel

believed that CPT code 10030 would be more appropriately assigned to APC 0007 (Level II Incision and Drainage).

We agree with the Panel's recommendation to reassign CPT code 10030 to APC 007. Therefore, we are proposing to reassign CPT code 10030 from APC 0006 to APC 0007 for the CY 2015 OPPS update. In light of the Panel's recommendation to reassign CPT code 49407 and the image-guided breast biopsy procedures to APC 0037, and our longstanding policy of reviewing, on an annual basis, the APC assignments for all services and items paid under the OPPS, we evaluated the geometric mean costs associated with the procedures assigned to the existing four needle biopsy APCs, specifically, APCs 0004 (Level I Needle Biopsy/Aspiration Except Bone Marrow), 0005, 0685 (Level III Needle Biopsy/Aspiration Except Bone Marrow), and 0037. Based on our review of the latest hospital outpatient claims data available for the proposed rule, we are proposing to reassign the procedures assigned to APCs 0685 and 0037 to either APC 0004 or APC 0005 based on clinical and resource homogeneity. With this proposed revision, there would be no procedures assigned to APCs 0685 or 0037. Therefore, we are proposing to delete APCs 0685 and 0037 for CY 2015. Consequently, for the CY 2015 OPPS update, we are proposing to use only two levels of needle biopsy APCs, specifically, APCs 0004 and 0005. Based on the proposal to reassign all of the procedures assigned to APCs 0685 and 0037 to either APC 0004 or APC 0005, we are proposing to reassign CPT code 49407 from APC 0685 to APC 0005 for CY 2015. Table 25 below shows the long descriptors for CPT codes 10030 and 49407, and their proposed status indicator and APC assignments for the CY 2015 OPPS update. The proposed CY 2015 payment rate for CPT codes 10030 and 49407 can be found in Addendum B to this CY 2015 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site).

TABLE 25—PROPOSED CY 2015 APC ASSIGNMENTS FOR CPT CODES 10030 AND 49407

CPT Code	Long descriptor	CY 2014 OPPS SI	CY 2014 OPPS APC	Proposed CY 2015 OPPS SI	Proposed CY 2015 OPPS APC
10030	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity, abdominal wall, neck), percutaneous.	T	0006	T	0007
49407	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, transvaginal or transrectal.	T	0685	T	0005

5. Cystourethroscopy and Other Genitourinary Procedures (APCs 0160, 0161, 0162, and 0163)

Every year we revise, if necessary, the APC assignments for procedure codes based on our analysis of the latest hospital outpatient claims data. Although we do not discuss every APC change in the proposed and final rules with comment period, these changes are listed in Addendum B to the proposed and final rules with comment period. Specifically, procedure codes with proposed revisions to the APC and/or status indicator assignments are assigned to comment indicator ''CH'' (Active HCPCS code in current year and next calendar year, status indicator and/or APC assignment has changed) in Addendum B to this proposed rule.

For the CY 2014 OPPS update, there are five levels of APCs that contain cystourethroscopy and genitourinary procedures. These APCs are listed in Table 26, along with their status indicator assignments for CY 2014.

TABLE 26—CY 2014 APCS CONTAINING CYSTOURETHROSCOPY AND GENITOURINARY PROCEDURES

CY 2014 APC	APC Title description	CY 2014 Status indicator
0160	Level I Cystourethroscopy and other Genitourinary Procedures	T
0161	Level II Cystourethroscopy and other Genitourinary Procedures	T
0162	Level III Cystourethroscopy and other Genitourinary Procedures	T
0163	Level IV Cystourethroscopy and other Genitourinary Procedures	T
0429	Level V Cystourethroscopy and other Genitourinary Procedures	T

For the CY 2015 OPPS update, based on our review of the latest hospital outpatient claims data available for this proposed rule, we are proposing to restructure the APCs containing cystourethroscopy and other genitourinary procedures to better reflect the resource costs and clinical characteristics of the procedures within each APC. This proposed restructuring results in the use of four APCs for the CY 2015 OPPS update, as compared to the five APCs used for the CY 2014 OPPS update. Specifically, based on our review and evaluation of the procedures assigned to these APCs and the latest hospital outpatient claims data, we are proposing to delete APC 0429 (Level V Cystourethroscopy and Other Genitourinary Procedures). We are proposing to reassign the procedures that were previously assigned to APC 0429 to either APC 0161 (Level I Cystourethroscopy and Other Genitourinary Procedures) or APC 0163 (Level IV Cystourethroscopy and other Genitourinary Procedures) for the CY 2015 OPPS update because we believe that these procedures would be more appropriately assigned to either APC based on their geometric mean costs. Further, we believe this proposed restructuring appropriately categorizes all of the cystourethroscopy and other genitourinary procedures that are comparable clinically and with respect to resource use within an APC group. In addition, we are proposing to delete APC 0169 (Lithotripsy) because the one

procedure, specifically the procedure described by CPT code 50590 (Lithotripsy, extracorporeal shock wave) that was assigned to this APC is proposed for reassignment to APC 0163.

In summary, we are proposing to restructure the APCs containing cystourethroscopy and other genitourinary procedures, and to use a four-level APC grouping to classify the procedures based on our analysis of the latest hospital outpatient claims data available for this proposed rule. In addition, we are proposing to delete APC 0169 and reassign CPT code 50590 to APC 0163 where it is more appropriately assigned based on resource costs and the similarity to the other procedures assigned to APC 0163. Table 27 shows the proposed APCs that contain cystourethroscopy and other genitourinary procedures, the APC titles, and the status indicator assignments for CY 2015. The proposed payment rates for the specific APCs listed in Table 27 can be found in Addendum A to this proposed rule, while the proposed payment rates for the specific cystourethroscopy and other genitourinary procedure codes can be found in Addendum B to this proposed rule (which are available via the Internet on the CMS Web site).

TABLE 27—PROPOSED CY 2015 APCS CONTAINING CYSTOURETHROSCOPY AND GENITOURINARY PROCEDURES

Proposed CY 2015 APC	APC Title description	Proposed CY 2015 Status indicator
0160	Level I Cystourethroscopy and other Genitourinary Procedures	T
0161	Level II Cystourethroscopy and other Genitourinary Procedures	T
0162	Level III Cystourethroscopy and other Genitourinary Procedures	T
0163	Level IV Cystourethroscopy and other Genitourinary Procedures	T

6. Wound Treatments and Services (APCs 0015 and 0327)

a. Epidermal Autograft (APC 0327)

In the CY 2014 OPPS/ASC final rule with comment period, we assigned CPT code 15110 to APC 0329 (Level IV Skin Repair), with a payment rate of approximately $2,260. This payment rate was derived from the latest hospital outpatient claims data used for CY 2014 ratesetting, which showed a geometric mean cost of approximately $2,174 based on 10 single claims (out of 29 total claims) for CPT code 15110.

As stated in section III.B. of this proposed rule, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS. Analysis of the latest hospital outpatient claims data available for this CY 2015 proposed rule showed a geometric mean cost of approximately $774 based on 90 single claims (out of 122 total claims) for CPT code 15110. Based on these recent data, we are proposing to reassign CPT code 15110 from APC 0329 to APC 0327 (Level II Skin Procedures), which has a geometric mean cost of approximately $451. We believe that APC 0327 is the most appropriate assignment for CPT code 15110 when considering its similarity to the other procedures in this APC.

In addition, we are proposing to revise the APC titles for the four skin repair APCs. Specifically, we are proposing to rename APC 0326 from ''Level I Skin Repair'' to ''Level I Skin Procedures,'' APC 0327 from ''Level II Skin Repair'' to ''Level II Skin Procedures,'' APC 0328 from ''Level III Skin Repair'' to ''Level III Skin Procedures,'' and APC 0329 from ''Level IV Skin Repair'' to ''Level IV Skin Procedures.''

Table 28 below shows the long descriptor, as well as the proposed CY 2015 APC and status indicator assignment, for CPT code 15110. The proposed CY 2015 payment rate for CPT code 15110 can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 28–PROPOSED CY 2015 APC AND STATUS INDICATOR FOR CPT CODE 15110

Procedure code	Long descriptor	CY 2014 SI	CY 2014 APC	Proposed CY 2015 SI	Proposed CY 2015 APC
15110	Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children.	T	0329	T	0327

b. Negative Pressure Wound Therapy (NPWT) (APC 0015)

We stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75001) that some commenters requested the reassignment of HCPCS codes G0456 and G0457 to a higher paying APC, specifically within the range of $450 to $500 because this range in amounts would adequately pay for the cost of providing negative pressure wound therapy (NPWT). We further stated in that same final rule with comment period that because HCPCS codes G0456 and G0457 were new codes for the CY 2013 OPPS update, we expected to have claims data available for these codes during the CY 2015 rulemaking cycle, and at which time we would reevaluate the APC assignments for these services in preparation for the CY 2015 rulemaking cycle.

We established HCPCS code G0456 and HCPCS code G0457 effective January 1, 2013, to provide a payment mechanism for NPWT services furnished through a disposable device. For the CY 2013 OPPS update, we assigned these services to APC 0016 (Level IV Debridement & Destruction), which had a CY 2013 payment rate of approximately $210. For the CY 2014 OPPS update, we continued to assign HCPCS codes G0456 and G0457 to APC 0016, which has a payment rate of approximately $275.

For the CY 2015 OPPS update, our analysis of the latest hospital outpatient claims data available for this proposed rule, which is based on claims submitted from January 1, 2013 through December 31, 2013, indicates that the geometric mean cost of APC 0013 is close to the geometric mean cost of APC 0015. Therefore, we are proposing to

combine these APCs by deleting APC 0013 and reassigning all of the procedures from APC 0013 to APC 0015, thereby retaining APC 0015. We are proposing to retitle the Debridement and Destruction APC series (excluding the title of APC 0012) as follows: APC 0015 (Level II Debridement and Destruction), APC 0016 (Level III Debridement and Destruction), and APC 0017 (Level IV Debridement and Destruction). The CY 2013 claims data available for this proposed rule also indicate that the resource costs for the services described by HCPCS codes G0456 and G0457 range between $152 and $193. Specifically, the geometric mean cost for HCPCS code G0456 is approximately $152 based on 4,509 single claims (out of 5,772 total claims), and approximately $193 for HCPCS code G0457 based on 386 single claims (out of 591 total claims). Based on our most recent claims data, we believe that a reassignment of HCPCS codes G0456 and G0457 from APC 0016 to APC 0015 (Level III Debridement & Destruction), which has a geometric mean cost of approximately $148, is most appropriate. Therefore, we are proposing to reassign HCPCS codes G0456 and G0457 from APC 0016 to APC 0015 for the CY 2015 OPPS update. Table 29 below shows the long descriptors as well as the proposed CY 2015 APC and status indicator assignments for HCPCS codes G0456 and G0457. The proposed CY 2015 payment rates for HCPCS codes G0456 and G0457 can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 29—PROPOSED CY 2015 APCS AND STATUS INDICATOR FOR HCPCS CODES G0456 AND G0457

HCPCS Code	Long descriptor	CY 2014 SI	CY 2014 APC	Proposed CY 2015 SI	Proposed CY 2015 APC
G0456	Negative pressure wound therapy, (eg, vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area less than or equal to 50 square centimeters.	T	0016	T	0015
G0457	Negative pressure wound therapy, (eg, vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area greater than 50 square centimeters.	T	0016	T	0015

7. Endoscopic Retrograde Cholangiopancreatography (ERCP) With Stent (APC 0384)

For the CY 2014 OPPS update, the AMA CPT Editorial Panel deleted CPT codes 43268 and 43269 describing an endoscopic retrograde cholangiopancreatography (ERCP) with stent placement into the biliary or pancreatic duct. New CPT codes 43274 and 43276 replaced deleted CPT codes 43268 and 43269, effective January 1, 2014. New CPT codes 43274 and 43276 describe an ERCP with stent placement into the biliary or pancreatic duct including dilation, guide wire passage, and sphincterotomy, when performed. As shown in Table 30, and as listed in Addendum B to the CY 2014 OPPS/ASC final rule with comment period, we assigned CPT codes 43274 and 43276 to APC 0151 (Endoscopic Retrograde Cholangio-Pancreatography (ERCP)), with a payment rate of $1,933.69 for CY 2014. In addition, as listed in Addendum B, both procedure codes were assigned to comment indicator ''NI'' to indicate that these codes were assigned interim APC and status indicator assignments that were subject to comment.

At the Panel's March 10, 2014 meeting, the Panel recommended that CMS reassign CPT codes 43274 and 43276 to APC 0384 (GI Procedures with Stents) at the earliest opportunity. We agree with the Panel's recommendation that CPT codes 43274 and 43276 should be reassigned to APC 0384. Therefore, we are proposing to reassign CPT codes 43274 and 43276 from APC 0151 to APC 0384 for the CY 2015 OPPS update. Table 30 below shows the long descriptors for CPT codes 43274 and 43276, and their proposed APC and status indicator assignments for the CY 2015 OPPS update. We note that APC 0384 is proposed as a comprehensive APC for CY 2015. We refer readers to section II.A.2.e. of this proposed rule for additional information on our comprehensive APC policy. The proposed CY 2015 payment rate for CPT codes 43274 and 43276 can be found in Addendum B to this CY 2015 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site).

TABLE 30—PROPOSED CY 2015 APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 43274 AND 43276

CPT code	Long descriptor	CY 2014 OPPS SI	CY 2014 OPPS APC	Proposed CY 2015 OPPS SI	Proposed CY 2015 OPPS APC
43274	Endoscopic retrograde cholangiopancreatography (ERCP); with placement of endoscopic stent into biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent.	T	0151	J1	0384

TABLE 30—PROPOSED CY 2015 APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 43274 AND 43276—Continued

CPT code	Long descriptor	CY 2014 OPPS SI	CY 2014 OPPS APC	Proposed CY 2015 OPPS SI	Proposed CY 2015 OPPS APC
43276	Endoscopic retrograde cholangiopancreatography (ERCP); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged.	T	0151	J1	0384

8. Radiation Therapy (APCs 0066, 0067, 0412, 0446, 0648, and 0667)

We are proposing several changes to the radiation therapy APCs for CY 2015. To correct a violation of the 2 times rule within APC 0664 (Level I Proton Beam Radiation Therapy), we are proposing to reassign CPT code 77520 from APC 0664 to APC 0412 (Level III Radiation Therapy). We believe that CPT code 77520 is both clinically similar and comparable in geometric mean cost to the other services assigned to APC 0412. We also are proposing to reassign CPT code 77522 from APC 0664 to proposed newly renamed APC 0667 (Level IV Radiation Therapy) because we believe that the procedure described by CPT code 77522 is both clinically similar and comparable in geometric mean cost to the other services assigned to APC 0667. Because there would be no other codes assigned to APC 0664 if these proposed reassignments are finalized, we also are proposing to delete APC 0664 for CY 2015. In addition, we are proposing to rename existing APC 0667 to ''Level IV Radiation Therapy'' (instead of using the existing title of ''Level II Proton Beam Radiation Therapy''), to make the title consistent with other APCs in the radiation therapy series. In conjunction with this proposed change, we are proposing to reassign the following three services to proposed newly renamed APC 0667 for CY 2015: CPT codes 77522, 77523, and 77525.

We also are proposing to delete APC 0065 (IORT, MRgFUS, and MEG) because we are proposing to reassign the services assigned to this APC to more appropriate APCs based on clinical similarities and comparable geometric mean cost. Specifically, we are proposing to reassign the Magnetoencephalography (MEG) CPT codes 95965 and 95966 from APC 0065 to APC 0446 (Level IV Nerve and Muscle Services), which would only contain MEG services. We are proposing to reassign Intraoperative Radiation Therapy (IORT) CPT codes 77424 and 77425 to comprehensive APC 0648 (Level IV Breast and Skin Surgery). We refer readers to section II.A.2.e. of this proposed rule for a discussion of comprehensive APCs and the APC assignment of IORT services. In addition, we are proposing to reassign the Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) HCPCS codes C9734, 0071T, and 0072T, and CPT code 0301T from APC 0065 to APC 0066, which we are proposing to rename ''Level V Radiation Therapy.'' We understand that the MRgFUS services are not the same as radiation therapy, but assigning these services to APC 0066 aligns with the assignment of certain stereotactic radiosurgery services (namely the procedure described by HCPCS code G0339 and successor CPT code 77373) that were grouped with MRgFUS services prior to CY 2014. Finally, we are proposing to rename APC 0067 from ''Level II Stereotactic Radiosurgery'' to ''Single Session Cranial Stereotactic Radiosurgery'', which we are proposing as a comprehensive APC. For a further discussion regarding the services assigned to APC 0067, we refer readers to section II.A.2.e. of this proposed rule.

IV. Proposed OPPS Payment for Devices

A. Proposed Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

a. Background

Section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. This pass-through payment eligibility period begins with the first date on which transitional pass-through payments may be made for any medical device that is described by the category. We may establish a new device category for pass-through payment in any quarter. Under our established policy, we base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category, which is the first date on which pass-through payment may be made for any medical device that is described by such category. We propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update.

We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763). Brachytherapy sources, which are now separately paid in accordance with section 1833(t)(2)(H) of the Act, are an exception to this established policy.

There currently is one device category eligible for pass-through payment. This device category is described by HCPCS code C1841 (Retinal prosthesis, includes all internal and external components), which we made effective for pass-through payment as of October 1, 2013.

b. Proposed CY 2015 Policy

As indicated earlier, a category of devices may be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. There is one device category eligible for pass-through payment at this time, described by HCPCS code C1841, which we made effective for pass-through payment as of October 1, 2013. At the end of CY 2015, the device category described by HCPCS code C1841 will have been eligible for pass-through payment for more than 2 years. Therefore, we are proposing an expiration date for pass-through payment for HCPCS code C1841 of December 31, 2015. We are proposing that, effective January 1, 2016, HCPCS code C1841 will no longer be eligible for pass-through payment status. In accordance with our established policy, we are proposing to package the cost of HCPCS code C1841 after December 31, 2015, into the costs related to the

procedures with which it is reported in our claims data.

If we create new device categories for pass-through payment status during the remainder of CY 2014 or during CY 2015, we will propose future expiration dates in accordance with the statutory requirement that they be eligible for pass-through payments for at least 2 years, but not more than 3 years, from the date on which pass-through payment for any medical device described by the category may first be made.

2. Proposed Provisions for Reducing Transitional Pass-Through Payments To Offset Costs Packaged Into APC Groups

a. Background

Section 1833(t)(6)(D)(ii) of the Act sets the amount of additional pass-through payment for an eligible device as the amount by which the hospital's charges for a device, adjusted to cost (the cost of the device) exceeds the portion of the otherwise applicable Medicare outpatient department fee schedule amount (the APC payment amount) associated with the device. We have an established policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments (66 FR 59904) for purposes of estimating the portion of the otherwise applicable APC payment amount associated with pass-through devices. For eligible device categories, we deduct an amount that reflects the portion of the APC payment amount that we determine is associated with the cost of the device, defined as the device APC offset amount, from the charges adjusted to cost for the device, as provided by section 1833(t)(6)(D)(ii) of the Act, to determine the eligible device's pass-through payment amount. We have consistently used an established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC rates (72 FR 66751 through 66752). We establish and update the applicable device APC offset amounts for newly eligible pass-through device categories through the transmittals that implement the quarterly OPPS updates.

Currently, we have published a list of all procedural APCs with the CY 2014 portions (both percentages and dollar amounts) of the APC payment amounts that we determine are associated with the cost of devices on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The dollar amounts are used as the device APC offset amounts. In addition, in accordance with our established practice, the device APC offset amounts in related APCs are used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices, as specified in our regulations at § 419.66(d).

Beginning in CY 2010, we include packaged costs related to implantable biologicals in the device offset calculations in accordance with our policy that the pass-through evaluation process and payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only (74 FR 60476).

b. Proposed CY 2015 Policy

We are proposing to continue, for CY 2015, our established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to (that is, reflect) the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC payment rates. We are proposing to continue our policy, for CY 2015, that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only. The rationale for this policy is provided in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477). We also are proposing to continue our established policies for calculating and setting the device APC offset amounts for each device category eligible for pass-through payment. In addition, we are proposing to continue our established policy to review each new device category on a case-by-case basis to determine whether device costs associated with the new category are already packaged into the existing APC structure. If device costs packaged into the existing APC structure are associated with the new category, we are proposing to deduct the device APC offset amount from the pass-through payment for the device category. As stated earlier, these device APC offset amounts also would be used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices (§ 419.66(d)).

For CY 2015, we also are proposing to continue our policy established in CY 2010 to include implantable biologicals in our calculation of the device APC offset amounts. In addition, we are proposing to continue to calculate and set any device APC offset amount for any new device pass-through category that includes a newly eligible implantable biological beginning in CY 2015 using the same methodology we have historically used to calculate and set device APC offset amounts for device categories eligible for pass-through payment, and to include the costs of implantable biologicals in the calculation of the device APC offset amounts (78 FR 43596).

In addition, we are proposing to update the list of all procedural APCs with the final CY 2015 portions of the APC payment amounts that we determine are associated with the cost of devices on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* so that this information is available for use by the public in developing potential CY 2015 device pass-through payment applications and by CMS in reviewing those applications.

B. Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

1. Background

To ensure equitable payment when the hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals are instructed to report no cost/full credit cases using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, the hospital is instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of

device or to a different type of device) with a full credit for the device being replaced, the hospital is instructed to report as the device charge the difference between its usual charge for the device being implanted and its usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals are instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduce OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limit the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim.

2. Proposed Policy for CY 2015

For CY 2015, we are proposing to continue our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Specifically, for CY 2015, we are proposing to continue to reduce the OPPS payment, for the applicable APCs listed below in Table 31, by the full or partial credit a provider receives for a replaced device. Under this proposed policy, hospitals would continue to be required to report the amount of the credit in the amount portion for ''FD'' when the hospital receives a credit for a replaced device listed in Table 32 that is 50 percent or greater than the cost of the device.

For CY 2015, we also are proposing to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which our proposed CY 2015 policy would apply (71 FR 68072 through 68077). Specifically: (1) All procedures assigned to the selected APCs must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and (3) the device offset amount must be significant, which, for purposes of this policy, is defined as exceeding 40 percent of the APC cost. We also are proposing to continue to restrict the devices to which the APC payment adjustment would apply to a specific set of costly devices to ensure that the adjustment would not be triggered by the implantation of an inexpensive device whose cost would not constitute a significant proportion of the total payment rate for an APC. We continue to believe these criteria are appropriate because no cost devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost.

We examined the offset amounts calculated from the CY 2015 proposed rule data and the clinical characteristics of the proposed CY 2015 APCs to determine which APCs meet the criteria for CY 2015. Table 31 below lists the proposed APCs to which the proposed payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2015. Table 32 below lists the proposed devices to which the proposed payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2015.

We are proposing to update the lists of APCs and devices to which the proposed no cost/full credit and partial credit device adjustment policy would apply for CY 2015, consistent with the three criteria discussed earlier in this section, based on the final CY 2013 claims data available for the CY 2015 OPPS/ASC final rule with comment period.

TABLE 31—PROPOSED APCS TO WHICH THE PROPOSED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2015

Proposed CY 2015 APC	Proposed CY 2015 APC title
0039	Level III Neurostimulator & Related Procedures.
0061	Level II Neurostimulator & Related Procedures.
0064	Level III Treatment Fracture/Dislocation.
0089	Level III Pacemaker and Similar Procedures.
0090	Level II Pacemaker and Similar Procedures.
0107	Level I ICD and Similar Procedures.
0108	Level II ICD and Similar Procedures.
0227	Implantation of Drug Infusion Device.
0229	Level II Endovascular Procedures.
0259	Level VII ENT Procedures.
0293	Level IV Intraocular Procedures.
0318	Level IV Neurostimulator & Related Procedures.
0319	Level III Endovascular Procedures.
0351	Level V Intraocular Procedures.
0385	Level I Urogenital Procedures.
0386	Level II Urogenital Procedures.
0425	Level V Musculoskeletal Procedures Except Hand and Foot.
0434	Cardiac Defect Repair.
0655	Level IV Pacemaker and Similar Procedures.

TABLE 32—PROPOSED DEVICES TO WHICH THE PROPOSED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2015

Proposed CY 2015 device HCPCS code	Proposed CY 2015 short descriptor
C1721	AICD, dual chamber.
C1722	AICD, single chamber.
C1728	Cath, brachytx seed adm.
C1764	Event recorder, cardiac.
C1767	Generator, neurostim, imp.
C1771	Rep dev, urinary, w/sling.
C1772	Infusion pump, programmable.

TABLE 32—PROPOSED DEVICES TO WHICH THE PROPOSED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2015—Continued

Proposed CY 2015 device HCPCS code	Proposed CY 2015 short descriptor
C1776	Joint device (implantable).
C1777	Lead, AICD, endo single coil.
C1778	Lead, neurostimulator.
C1779	Lead, pmkr, transvenous VDD.
C1785	Pmkr, dual, rate-resp.
C1786	Pmkr, single, rate-resp.
C1789	Prosthesis, breast, imp.
C1813	Prosthesis, penile, inflatab.
C1815	Pros, urinary sph, imp.
C1818	Integrated keratoprosthesis.
C1820	Generator, neuro rechg bat sys.
C1840	Lens, intraocular (telescopic).
C1881	Dialysis access system.
C1882	AICD, other than sing/dual.
C1891	Infusion pump, non-prog, perm.
C1895	Lead, AICD, endo dual coil.
C1896	Lead, AICD, non sing/dual.
C1897	Lead, neurostim, test kit.
C1898	Lead, pmkr, other than trans.
C1899	Lead, pmkr/AICD combination.
C1900	Lead coronary venous.
C2619	Pmkr, dual, non rate-resp.
C2620	Pmkr, single, non rate-resp.
C2621	Pmkr, other than sing/dual.
C2622	Prosthesis, penile, non-inf.
C2626	Infusion pump, non-prog, temp.
C2631	Rep dev, urinary, w/o sling.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout this proposed rule, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. ''Biological'' as used in this proposed rule includes ''biological product'' or ''biologic'' as defined in the Public Health Service Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this provision requires the Secretary to make additional payments to hospitals for: Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; urrent drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to drugs or biologicals that are outpatient hospital services under Part B for which payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2015 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this proposed rule, which are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. If the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, the pass-through payment amount is determined by the Secretary to be equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary. However, we note that the Part B drug competitive acquisition program (CAP) has been postponed since CY 2009, and such a program has not been reinstated for CY 2015.

This methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological. Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this proposed rule, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

The pass-through application and review process for drugs and biologicals is explained on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*.

2. Proposed Drugs and Biologicals With Expiring Pass-Through Status in CY 2014

We are proposing that the pass-through status of 9 drugs and biologicals would expire on December 31, 2014, as listed in Table 33 below. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2014. These drugs and biologicals were approved for pass-through status on or before January 1, 2013. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through status (specifically, diagnostic radiopharmaceuticals; contrast agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed at $90 for CY 2015), as discussed further in section V.B.2. of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we would provide separate payment at the applicable

relative ASP-based payment amount (which is proposed at ASP+6 percent for CY 2015, as discussed further in section V.B.3. of this proposed rule).

TABLE 33—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2014

Proposed CY 2015 HCPCS Code	Proposed CY 2015 long descriptor	Proposed CY 2015 SI	Proposed CY 2015 APC
C9290	Injection, bupivicaine liposome, 1 mg	N	N/A
C9293	Injection, glucarpidase, 10 units	K	9293
J0178	Injection, aflibercept, 1 mg vial	K	1420
J0716	Injection, centruroides (scorpion) immune f(ab)2, up to 120 milligrams	K	1431
J9019	Injection, asparaginase (erwinaze), 1,000 iu	K	9289
J9306	Injection, pertuzumab, 1 mg	K	1471
Q4131	EpiFix, per square centimeter	N	N/A
Q4132	Grafix core, per square centimeter	N	N/A
Q4133	Grafix prime, per square centimeter	N	N/A

3. Proposed Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Status in CY 2015

We are proposing to continue pass-through status in CY 2015 for 22 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2014. These drugs and biologicals, which were approved for pass-through status between January 1, 2013 and July 1, 2014, are listed in Table 34 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through April 1, 2014 are assigned status indicator ''G'' in Addenda A and B to this proposed rule. Addenda A and B to this proposed rule are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at the physician's office payment rate of ASP+6 percent. We believe it is consistent with the statute to propose to continue to provide payment for drugs and biologicals with pass-through status at a rate of ASP+6 percent in CY 2015, which is the amount that drugs and biologicals receive under section 1842(o) of the Act.

Therefore, for CY 2015, we are proposing to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2015. We are proposing that a $0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2015 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: Contrast agents; diagnostic radiopharmaceuticals; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs; and biologicals that function as supplies when used in a surgical procedure), we are proposing that their pass-through payment amount would be equal to ASP+6 percent for CY 2015 because, if not on pass-through status, payment for these products would be packaged into the associated procedure.

In addition, we are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2015 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

In CY 2015, as is consistent with our CY 2014 policy for diagnostic and therapeutic radiopharmaceuticals, we are proposing to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through status based on the ASP methodology. As stated above, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through status during CY 2015, we are proposing to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we are proposing to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information is also not available, we are proposing to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

As discussed in more detail in section II.A.3. of this proposed rule, we implemented a policy whereby payment for the following nonpass-through items is packaged into payment for the associated procedure: Diagnostic radiopharmaceuticals; contrast agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure. We are proposing to continue the packaging of these items, regardless of their per day cost, in CY 2015. As stated earlier, pass-through payment is the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Because payment for a drug that is policy-packaged would otherwise be packaged if the product did not have pass-through status, we believe the otherwise applicable OPPS payment amount would be equal to the policy-packaged drug APC offset amount for the associated clinical APC in which the drug or biological is

utilized. The proposed calculation of the policy-packaged drug APC offset amounts is described in more detail in section V.A.4. of this proposed rule. It follows that the copayment for the nonpass-through payment portion (the otherwise applicable fee schedule amount that we would also offset from payment for the drug or biological if a payment offset applies) of the total OPPS payment for those drugs and biologicals would, therefore, be accounted for in the copayment for the associated clinical APC in which the drug or biological is used.

According to section 1833(t)(8)(E) of the Act, the amount of copayment associated with pass-through items is equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied. Therefore, as we did in CY 2014, we are proposing to continue to set the associated copayment amount to zero for CY 2015 for pass-through drugs and biologicals that would otherwise be packaged if the item did not have pass-through status.

The 22 drugs and biologicals that we are proposing to continue to have pass-through status for CY 2015 or have been granted pass-through status as of July 2014 are shown in Table 34 below.

TABLE 34—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2015

Proposed CY 2015 HCPCS code	CY 2015 Long descriptor	Proposed CY 2015 SI	Proposed CY 2015 APC
A9520	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	G	1463
C9021	Injection, obinutuzumab, 10 mg	G	1476
C9022	Injection, elosulfase alfa, 1mg	G	1480
C9132	Prothrombin complex concentrate (human), Kcentra, per i.u. of Factor IX activity	G	9132
C9133	Factor ix (antihemophilic factor, recombinant), Rixubus, per i.u.	G	1467
C9134	Injection, Factor XIII A-subunit, (recombinant), per 10 i.u.	G	1481
C9441	Injection, ferric carboxymaltose, 1 mg	G	9441
C9497	Loxapine, inhalation powder, 10 mg	G	9497
J1446	Injection, tbo-filgrastim, 5 micrograms	G	1447
J1556	Injection, immune globulin (Bivigam), 500 mg	G	9130
J3060	Injection, taliglucerase alfa, 10 units	G	9294
J7315	Mitomycin, ophthalmic, 0.2 mg	G	1448
J7316	Injection, Ocriplasmin, 0.125mg	G	9298
J7508	Tacrolimus, Extended Release, Oral, 0.1 mg	G	1465
J9047	Injection, carfilzomib, 1 mg	G	9295
J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
J9354	Injection, ado-trastuzumab emtansine, 1 mg	G	9131
J9371	Injection, Vincristine Sulfate Liposome, 1 mg	G	1466
J9400	Injection, Ziv-Aflibercept, 1 mg	G	9296
Q4121	Theraskin, per square centimeter	G	1479
Q4122	Dermacell, per square centimeter	G	1419
Q4127	Talymed, per square centimeter	G	1449

Note: Because the payment rates associated with these codes effective July 1, 2014, are not available to us in time for incorporation into the Addenda to this proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2014 OPPS quarterly update CR could not be included in Addendum B to this proposed rule.

4. Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals To Offset Costs Packaged Into APC Groups

a. Background

Prior to CY 2008, diagnostic radiopharmaceuticals and contrast agents were paid separately under the OPPS if their mean per day costs were greater than the applicable year's drug packaging threshold. In CY 2008 (72 FR 66768), we began a policy of packaging payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents as ancillary and supportive items and services into their associated nuclear medicine procedures. Therefore, beginning in CY 2008, nonpass-through diagnostic radiopharmaceuticals and contrast agents were not subject to the annual OPPS drug packaging threshold to determine their packaged or separately payable payment status, and instead all nonpass-through diagnostic radiopharmaceuticals and contrast agents were packaged as a matter of policy.

For CY 2014, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), we continued to package payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs and we began packaging all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure. These packaging policies were codified at 42 CFR 419.2(b) in CY 2014.

b. Proposed Payment Offset Policy for Diagnostic Radiopharmaceuticals

As previously noted, radiopharmaceuticals are considered to be drugs for OPPS pass-through payment purposes. As described above, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for diagnostic radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor radiopharmaceuticals in order to ensure no duplicate radiopharmaceutical payment is made.

In CY 2009, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals when considering a new diagnostic radiopharmaceutical for pass-through payment (73 FR 68638 through 68641). Specifically, we use the policy-packaged drug offset fraction for APCs containing

nuclear medicine procedures, calculated as 1 minus the following: The cost from single procedure claims in the APC after removing the cost for policy-packaged drugs divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through diagnostic radiopharmaceuticals that takes into consideration the otherwise applicable OPPS payment amount, we multiply the policy-packaged drug offset fraction by the APC payment amount for the nuclear medicine procedure with which the pass-through diagnostic radiopharmaceutical is used and, accordingly, reduce the separate OPPS payment for the pass-through diagnostic radiopharmaceutical by this amount. For CY 2015, as we did in CY 2014, we are proposing to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals.

There is currently one diagnostic radiopharmaceutical with pass-through status under the OPPS. HCPCS code A9520 (Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries) was granted pass-through status beginning October 1, 2013. We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for this product.

Table 35 below displays the proposed APCs to which nuclear medicine procedures would be assigned in CY 2015 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 35—PROPOSED APCS TO WHICH A DIAGNOSTIC RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2015

Proposed CY 2015 APC	Proposed CY 2015 APC title
0308	Positron Emission Tomography (PET) Imaging.
0377	Level II Cardiac Imaging.
0378	Level II Pulmonary Imaging.
0389	Level I Non-imaging Nuclear Medicine.
0390	Level I Endocrine Imaging.
0391	Level II Endocrine Imaging.
0392	Level II Non-imaging Nuclear Medicine.
0393	Hematologic Processing & Studies.
0394	Hepatobiliary Imaging.
0395	GI Tract Imaging.
0396	Bone Imaging.
0398	Level I Cardiac Imaging.
0400	Hematopoietic Imaging.
0401	Level I Pulmonary Imaging.
0402	Level II Nervous System Imaging.
0403	Level I Nervous System Imaging.
0404	Renal and Genitourinary Studies.
0406	Level I Tumor/Infection Imaging.
0408	Level III Tumor/Infection Imaging.
0414	Level II Tumor/Infection Imaging.

c. Proposed Payment Offset Policy for Contrast Agents

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for contrast agents an amount reflecting the portion of the APC payment associated with predecessor contrast agents in order to ensure no duplicate contrast agent payment is made.

In CY 2010, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor contrast agents when considering new contrast agents for pass-through payment (74 FR 60482 through 60484). Specifically, we use the policy-packaged drug offset fraction for procedural APCs, calculated as 1 minus the following: The cost from single procedure claims in the APC after removing the cost for policy packaged drugs divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through contrast agents that takes into consideration the otherwise applicable OPPS payment amount, we are proposing to multiply the policy packaged drug offset fraction by the APC payment amount for the procedure with which the pass-through contrast agent is used and, accordingly, reduce the separate OPPS payment for the pass-through contrast agent by this amount. For CY 2015, as we did in CY 2014, we are proposing to continue to apply our standard contrast agents offset policy to payment for pass-through contrast agents (78 FR 75017).

Although there are currently no contrast agents with pass-through status under the OPPS, we believe that a payment offset is necessary in the event that a new contrast agent is approved for pass-through status during CY 2015 in order to provide an appropriate transitional pass-through payment for new contrast agents. We are proposing to identify procedural APCs for which we expect a contrast offset could be applicable in the case of a pass-through contrast agent as any procedural APC with a policy-packaged drug amount greater than $20 that is not a nuclear medicine APC identified in Table 35 above, and these APCs are displayed in Table 36 below. The methodology used to determine a proposed threshold cost for application of a contrast agent offset policy is described in detail in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60483 through 60484). For CY 2015, we are proposing to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 36 of this proposed rule, a specific offset based on the procedural APC would be applied to payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

TABLE 36—PROPOSED APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2015

Proposed CY 2015 APC	Proposed CY 2015 APC title
0080	Diagnostic Cardiac Catheterization.
0082	Coronary or Non-Coronary Atherectomy.
0083	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization.
0093	Vascular Reconstruction/Fistula Repair.
0104	Transcatheter Placement of Intracoronary Stents.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0177	Level I Echocardiogram With Contrast.
0178	Level II Echocardiogram With Contrast.
0229	Level II Endovascular Revascularization of the Lower Extremity.
0278	Diagnostic Urography.
0279	Level II Angiography and Venography.
0280	Level III Angiography and Venography.
0283	Computed Tomography with Contrast.

TABLE 36—PROPOSED APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2015—Continued

Proposed CY 2015 APC	Proposed CY 2015 APC title
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast.
0333	Computed Tomography without Contrast followed by Contrast.
0334	Combined Abdomen and Pelvis CT with Contrast.
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast.
0375	Ancillary Outpatient Services When Patient Expires.
0383	Cardiac Computed Tomographic Imaging.
0388	Discography.
0442	Dosimetric Drug Administration.
0653	Vascular Reconstruction/Fistula Repair with Device.
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0662	CT Angiography.
0668	Level I Angiography and Venography.
8006	CT and CTA with Contrast Composite.
8008	MRI and MRA with Contrast Composite.

d. Proposed Payment Offset Policy for Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Procedure and Drugs and Biologicals That Function as Supplies When Used in a Surgical Procedure

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), we finalized our policy to package drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure. As a part of this policy, we specifically finalized that skin substitutes and stress agents used in myocardial perfusion imaging (MPI) be policy packaged in CY 2014, in addition to diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs (78 FR 75019). Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we finalized a policy for CY 2014 to deduct from the pass-through payment for skin substitutes and stress agents an amount reflecting the portion of the APC payment associated with predecessor skin substitutes and stress agents in order to ensure no duplicate skin substitute or stress agent payment is made (78 FR 75019).

In CY 2014, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor skin substitutes or stress agents when considering a new skin substitute or stress agent for pass-through payment (78 FR 75019). Specifically, in the case of pass-through skin substitutes, we use the policy-packaged drug offset fraction for skin substitute procedural APCs, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy-packaged drugs divided by the cost from single procedure claims in the APC. Because policy packaged radiopharmaceuticals also would be included in the drug offset fraction for the APC to which MPI procedures are assigned, in the case of pass-through stress agents, we use the policy-packaged drug offset fraction for the procedural APC, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy-packaged drugs excluding policy-packaged diagnostic radiopharmaceuticals divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through skin substitutes and pass-through stress agents that takes into consideration the otherwise applicable OPPS payment amount, we multiply the policy-packaged drug offset fraction by the APC payment amount for the procedure with which the pass-through skin substitute or pass-through stress agent is used and, accordingly, reduce the separate OPPS payment for the pass-through skin substitute or pass-through stress agent by this amount (78 FR 75019). For CY 2015, as we did in CY 2014, we are proposing to continue to apply the skin substitute and stress agent offset policy to payment for pass-through skin substitutes and stress agents.

There are currently six skin substitutes (HCPCS codes Q4121, Q4122, Q4127, Q4131, Q4132, and Q4133) with pass-through status under the OPPS. We currently apply the established skin substitute payment offset policy to pass-through payment for these products. Table 37 below displays the proposed APCs to which skin substitute procedures would be assigned in CY 2015 and for which we expect that an APC offset could be applicable in the case of skin substitutes with pass-through status.

Although there are currently no stress agents with pass-through status under the OPPS, we believe that a payment offset is necessary in the event that a new stress agent is approved for pass-through status during CY 2015 in order to provide an appropriate transitional pass through payment for new stress agents. Table 38 below displays the proposed APCs to which MPI procedures would be assigned in CY 2015 and for which we expect that an APC offset could be applicable in the case of a stress agent with pass-through status.

We are proposing to continue to post annually on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

TABLE 37—PROPOSED APCS TO WHICH A SKIN SUBSTITUTE OFFSET MAY BE APPLICABLE FOR CY 2015

Proposed CY 2015 APC	Proposed CY 2015 APC Title
0328	Level III Skin Repair.
0329	Level IV Skin Repair.

TABLE 38—PROPOSED APCS TO WHICH A STRESS AGENT OFFSET MAY BE APPLICABLE FOR CY 2015

Proposed CY 2015 APC	Proposed CY 2015 APC Title
0100	Cardiac Stress Tests.
0377	Level II Cardiac Imaging.

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

1. Background

Under the CY 2013 OPPS, we currently pay for drugs, biologicals, and

radiopharmaceuticals that do not have pass-through status in one of two ways: As a packaged payment included in the payment for the associated service, or as a separate payment (individual APCs). We explained in the April 7, 2000 OPPS final rule with comment period (65 FR 18450) that we generally package the cost of drugs and radiopharmaceuticals into the APC payment rate for the procedure or treatment with which the products are usually furnished. Hospitals do not receive separate payment for packaged items and supplies, and hospitals may not bill beneficiaries separately for any packaged items and supplies whose costs are recognized and paid within the national OPPS payment rate for the associated procedure or service.

Packaging costs into a single aggregate payment for a service, procedure, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility.

2. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Background

As indicated in section V.B.1. of this proposed rule, in accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $90 for CY 2014.

Following the CY 2007 methodology, for this CY 2015 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2015 and rounded the resulting dollar amount ($91.46) to the nearest $5 increment, which yielded a figure of $90. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from CMS' Office of the Actuary (OACT). We refer below to this series generally as the PPI for Prescription Drugs.

Based on the calculations described above, we are proposing a packaging threshold for CY 2015 of $90. (For a more detailed discussion of the OPPS drug packaging threshold and the use of the PPI for Prescription Drugs, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086).)

b. Proposed Cost Threshold for Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals (''Threshold-Packaged Drugs'')

To determine the proposed CY 2015 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2013 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2013 claims processed before January 1, 2014 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.2.c. of this proposed rule, or for the following policy-packaged items that we are proposing to continue to package in CY 2015: Diagnostic radiopharmaceuticals; contrast agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2015, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 70 FR 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we are proposing for separately payable drugs and biologicals for CY 2015, as discussed in more detail in section V.B.3.b. of this proposed rule) to calculate the CY 2015 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2013 (data that were used for payment purposes in the physician's office setting, effective April 1, 2014) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2015, we are proposing to use payment rates based on the ASP data from the fourth quarter of CY 2013 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) because these are the most recent data available for use at the time of development of this proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2014. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2013 hospital claims data to determine their per day cost.

We are proposing to package items with a per day cost less than or equal to $90, and identify items with a per day cost greater than $90 as separately payable. Consistent with our past practice, we crosswalked historical OPPS claims data from the CY 2013 HCPCS codes that were reported to the CY 2014 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for payment in CY 2015.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in the CY 2015 OPPS/ASC final rule with comment period, we are proposing to use ASP data from the first quarter of

CY 2014, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2014, along with updated hospital claims data from CY 2013. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for the CY 2015 OPPS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B to the final rule with comment period will be based on ASP data from the second quarter of CY 2014. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2014. These payment rates would then be updated in the January 2015 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2015. For items that do not currently have an ASP-based payment rate, we are proposing to recalculate their mean unit cost from all of the CY 2013 claims data and updated cost report information available for the CY 2015 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this CY 2015 OPPS/ASC proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the CY 2015 OPPS/ASC final rule with comment period. Under such circumstances, we are proposing to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the proposed CY 2015 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2014. Specifically, for CY 2015, consistent with our historical practice, we are proposing to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2014 and that are proposed for separate payment in CY 2015, and that then have per day costs equal to or less than the CY 2015 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2015 final rule, would continue to receive separate payment in CY 2015.
- HCPCS codes for drugs and biologicals that were packaged in CY 2014 and that are proposed for separate payment in CY 2015, and that then have per day costs equal to or less than the CY 2015 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2015 final rule, would remain packaged in CY 2015.
- HCPCS codes for drugs and biologicals for which we are proposing packaged payment in CY 2015 but then have per day costs greater than the CY 2015 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2015 final rule, would receive separate payment in CY 2015.

c. Proposed High/Low Cost Threshold for Packaged Skin Substitutes

In the CY 2014 OPPS/ASC final rule, we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package drugs and biologicals that function as supplies when used in a surgical procedure (78 FR 74938). We also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, for packaging purposes, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). For CY 2014, assignment to the high cost or low cost skin substitute group depended upon a comparison of the July 2013 ASP + 6 percent payment amount for each skin substitute to the weighted average payment per unit for all skin substitutes (weighted average was calculated using the skin substitute utilization from the CY 2012 claims data and the July 2013 ASP + 6 percent payment amounts, which are also the payment amounts in Addendum B to the CY 2014 OPPS/ASC final rule with comment period). The high/low cost skin substitute threshold for CY 2014 is $32 per cm^2. Skin substitutes that had a July 2013 ASP + 6 percent amount above $32 per cm^2 were classified in the high cost group and those with a July 2013 ASP + 6 percent amount at or below $32 per cm^2 were classified in the low cost group. Any new skin substitutes without pricing information are assigned to the low cost category until pricing information is available to compare to the $32 per cm^2 threshold for CY 2014. Skin substitutes with pass-through status are assigned to the high cost category, with an offset applied as described in section II.C.6. of this proposed rule.

After the effective date of the CY 2014 packaging policy, some skin substitute manufacturers brought the following issues to our attention regarding the current methodology for determining the high cost/low cost threshold:

- Using ASP to determine a product's placement in the high or low cost category may unfairly disadvantage the limited number of skin substitute products that are sold in large sizes (that is, above 150 cm^2). Large size skin substitute products are primarily used for burns that are treated on an inpatient basis. These manufacturers contend that non-linear pricing for skin substitute products sold in both large and small sizes results in lower per cm^2 prices for large sizes. Therefore, the use of ASP data to categorize products into high and low cost categories can result in placement of products that have significant inpatient use of the large, lower-priced (per cm^2) sizes into the low cost category, even though these large size products are not often used in the hospital outpatient department.
- Using a weighted average ASP to establish the high/low cost categories, combined with the drug pass-through policy, will lead to unstable high/low cost skin substitute categories in the future. According to one manufacturer, under our current policy manufacturers with products on pass-through have an incentive to set a very high price because hospitals are price-insensitive to products paid with pass-through payments. As these new high priced pass-through skin substitutes capture more market share, the weighted average ASP high/low cost threshold could escalate rapidly resulting in a shift in the assignment of many skin substitutes from the high cost category to the low cost category.

We agree with stakeholder concerns regarding the potential instability of the high/low cost categories associated with the drug pass-through policy, as well as stakeholder concerns about the inclusion of large-sized products that are primarily used for inpatients in the ASP calculation, when ASP is used to establish the high/low cost categories. As an alternative to using ASP data, we believe that establishing the high/low cost threshold using the weighted average mean unit cost (MUC) for all skin substitute products from claims data may provide more stable high/low cost categories and will resolve the issue associated with large sized products because the MUC will be derived from outpatient claims only. The threshold would be based on costs from outpatient claims data instead of manufacturer

reported sales prices that would not include larger sizes primarily used for inpatient burn cases.

Therefore, we are proposing to maintain the high/low cost APC structure for skin substitute procedures in CY 2015 but we are proposing to revise the current methodology used to establish the high/low cost threshold. For CY 2015, we are proposing to establish the high/low cost threshold based on the weighted average MUC for all skin substitutes using CY 2013 claims (which is proposed to be $27 per cm^2). Skin substitutes with a MUC above $27 per cm^2 using CY 2013 claims are proposed to be classified in the high cost group and those with a MUC at or below $27 per cm^2 are proposed to be classified in the low cost group. Table 39 below shows the current high/low cost status for each skin substitute product and the proposed 2015 high/low cost status based on the weighted average MUC threshold of $27. We are proposing to continue the current policy that skin substitutes with pass-through status will be assigned to the high cost category for CY 2015. Skin substitutes with pricing information but without claims data to calculate a MUC will be assigned to either the high or low cost category based on the product's ASP + 6 percent payment rate. If ASP is not available then we will use WAC + 6 percent or 95 percent of AWP to assign a product to either the high or low cost category. We are also proposing that any new skin substitute without pricing information be assigned to the low cost category until pricing information is available to compare to the proposed $27 per cm^2 threshold for CY 2015.

TABLE 39—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS

CY 2014 HCPCS Code	CY 2014 Short descriptor	Proposed CY 2015 SI	CY 2014 High/low status based on weighted ASP	Proposed CY 2015 High/low status based on weighted MUC
C9358	SurgiMend, fetal	N	Low	Low
C9360	SurgiMend, neonatal	N	Low	Low
C9363	Integra Meshed Bil Wound Mat	N	Low	High
Q4101	Apligraf	N	High	High
Q4102	Oasis wound matrix	N	Low	Low
Q4103	Oasis burn matrix	N	Low	Low
Q4104	Integra BMWD	N	Low	High
Q4105	Integra DRT	N	Low	High
Q4106	Dermagraft	N	High	High
Q4107	Graftjacket	N	High	High
Q4108	Integra matrix	N	Low	High
Q4110	Primatrix	N	High	High
Q4111	Gammagraft	N	Low	Low
Q4115	Alloskin	N	Low	Low
Q4116	Alloderm	N	High	High
Q4117	Hyalomatrix	N	Low	Low
Q4119	Matristem wound matrix	N	Low	Low
Q4120	Matristem burn matrix	N	Low	Low
Q4121	Theraskin	G	High	High
Q4122	Dermacell	G	High	High
Q4123	Alloskin	N	Low	Low
Q4124	Oasis tri-layer wound matrix	N	Low	Low
Q4125	Arthroflex	N	High	High
Q4126	Memoderm/derma/tranz/integup	N	High	High
Q4127	Talymed	G	High	High
Q4128	Flexhd/Allopatchhd/matrixhd	N	Low	High
Q4129	Unite biomatrix	N	Low	Low
Q4131	Epifix	N	High	High
Q4132	Grafix core	N	High	High
Q4133	Grafix prime	N	High	High
Q4134	hMatrix	N	High	High
Q4135	Mediskin	N	Low	High
Q4136	EZderm	N	Low	Low
Q4137	Amnioexcel or biodexcel, 1cm	N	Low	Low
Q4138	BioDfence DryFlex, 1cm	N	Low	Low
Q4140	Biodfence 1cm	N	Low	Low
Q4141	Alloskin ac, 1 cm	N	Low	Low
Q4142	Xcm biologic tiss matrix 1cm	N	Low	Low
Q4143	Repriza, 1cm	N	Low	Low
Q4146	Tensix, 1cm	N	Low	Low
Q4147	Architect ecm, 1cm	N	High	High
Q4148	Neox 1k, 1cm	N	High	High

d. Proposed Pass-Through Evaluation Process for Skin Substitutes

At the beginning of the OPPS, skin substitutes were originally evaluated for pass-through status using the medical device pass-through process. Since 2001, skin substitutes have been evaluated for pass-through status through the drug, biological, and radiopharmaceutical pass-through process. There are currently 50 distinct HCPCS codes describing skin

substitutes, and of these 50 products 17 products that are listed in Table 40 have had or currently have pass-through status.

TABLE 40—SKIN SUBSTITUTES THAT HAVE HAD OR CURRENTLY HAVE PASS-THROUGH STATUS

CY 2014 HCPCS	CY 2014 Short descriptor	Pass-through expiration date
C9358	SurgiMend, fetal	12/31/2010
C9360	SurgiMend, neonatal	12/31/2011
C9363	Integra Meshed Bil Wound Mat	12/31/2011
Q4101	Apligraf	12/31/2002
Q4104	Integra BMWD	12/31/2006
Q4105	Integra DRT	12/31/2006
Q4106	Dermagraft	03/31/2005
Q4107	Graftjacket	12/31/2006
Q4108	Integra matrix	12/31/2010
Q4110	Primatrix	12/31/2008
Q4121	Theraskin	12/31/2016
Q4122	Dermacell	12/31/2015
Q4124	Oasis tri-layer wound matrix	12/31/2013
Q4127	Talymed	12/31/2015
Q4131	Epifix	12/31/2014
Q4132	Grafix core	12/31/2014
Q4133	Grafix prime	12/31/2014

As discussed above, in CY 2014 we packaged all skin substitutes under the policy that packages all drugs and biologicals that function as supplies when used in a surgical procedure (78 FR 74938). Therefore, we consider skin substitutes to be a type of surgical supply in the HOPD. This packaging policy was partly based on a comparison to implantable biologicals, which are similar in composition and clinical use to skin substitutes (78 FR 74931). In CY 2009, we finalized a policy to package payment for implantable biologicals into the payment for the associated surgical procedure (73 FR 68635). In CY 2010, we finalized a policy to evaluate implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) for pass-through payment through the medical device pass-through evaluation process, as implantable biologicals function as implantable devices (74 FR 60473). Implantable devices are considered supplies in the OPPS (65 FR 18443), and as noted above, we finalized a packaging policy in the CY 2014 OPPS/ASC final rule with comment period that considers skin substitutes a type of surgical supply. Many skin substitutes are FDA-approved or cleared as devices. The similarities between implantable biologicals and skin substitutes were a key factor in packaging (like we did beginning in 2009 with implantable biologicals) skin substitutes into the associated surgical procedure (78 FR 74932). These similarities between these classes of products also support similar treatment under the OPPS device pass-through process, which has been the evaluation methodology for implantable biologicals since 2010.

In view of these considerations, we are proposing that applications for pass-through payment for skin substitutes be evaluated using the medical device pass-through process and payment methodology. As a result of this proposal, we are proposing that the last skin substitute pass-through applications evaluated using the drug and biological pass-through evaluation process would be those with an application deadline of September 1, 2014, and an earliest effective date of January 1, 2015. Therefore, in light of this proposal, we would change the December 1, 2014 pass-through application deadline (for an earliest effective date of April 1, 2015) for both drugs and biologicals and devices to January 15, 2015, in order to provide sufficient time for applicants to adjust to the new policies and procedures in effect as of January 1, 2015. We believe that this approach is more appropriate because, although skin substitutes have characteristics of both surgical supplies and biologicals, we believe that, for pass-through purposes, skin substitutes are best characterized as surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical supplies, including implantable biologicals. Thus, if this proposal is finalized, beginning on and after January 1, 2015, new skin substitutes would no longer be eligible to submit biological pass-through applications; rather, such applications for pass-through payment would be evaluated using the medical device pass-through evaluation process, for which payment is based on charges reduced to cost from claims. We refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/* to view the device pass-through application requirements and review criteria that would apply to the evaluation of all skin substitute product applications for pass-through status beginning on or after January 1, 2015. Those skin substitutes that are approved for pass-through status as biologicals effective on or before January 1, 2015, would continue to be considered pass-through biologicals for the duration of their period of pass-through payment.

We also are proposing to revise our regulations at §§ 419.64 and 419.66 to reflect this proposed new policy. Specifically, we are proposing to revise § 419.64 by deleting the existing paragraph (a)(4)(iv) text because it is currently outdated and adding new text at paragraph (a)(4)(iv) to exclude skin substitutes from consideration for drug and biological pass-through payment unless pass-through payment for a product as a biological is made on or before January 1, 2015, to allow these products to complete their period of pass-through payment as biologicals. We are proposing to modify the regulation at § 419.66(b)(3) to add that a pass-through device may be applied in or on a wound or other skin lesion, and we are simplifying the language that

''whether or not it remains with the patient when the patient is released from the hospital'' to read ''either permanently or temporarily.'' We also are proposing to delete the current example in § 419.66(b)(4)(iii) of the regulations regarding the exclusion of materials, for example, biological or synthetic materials, that may be used to replace human skin from device pass-through payment eligibility.

We invite public comment on these proposals.

e. Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66776), we began recognizing, for OPPS payment purposes, multiple HCPCS codes reporting different dosages for the same covered Part B drugs or biologicals in order to reduce hospitals' administrative burden by permitting them to report all HCPCS codes for drugs and biologicals. In general, prior to CY 2008, the OPPS recognized for payment only the HCPCS code that described the lowest dosage of a drug or biological. During CYs 2008 and 2009, we applied a policy that assigned the status indicator of the previously recognized HCPCS code to the associated newly recognized code(s), reflecting the packaged or separately payable status of the new code(s).

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believed that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we are proposing to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2015.

For CY 2015, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2013 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this CY 2015 OPPS/ASC proposed rule and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2013 claims data to make the packaging determinations for these drugs: HCPCS code J3471 (Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)) and HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to $90 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than $90 (so that all HCPCS codes for the same drug or biological would be separately payable).

The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply is displayed in Table 41 below.

TABLE 41—PROPOSED HCPCS CODES TO WHICH THE CY 2015 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

Proposed CY 2015 HCPCS code	Proposed CY 2015 long descriptor	Proposed CY 2015 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1070	Injection, testosterone cypionate, up to 100 mg	N
J1080	Injection, testosterone cypionate, 1 cc, 200 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	N
J1560	Injection, gamma globulin, intramuscular over 10 cc	N
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J2270	Injection, morphine sulfate, up to 10 mg	N
J2271	Injection, morphine sulfate, 100 mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3120	Injection, testosterone enanthate, up to 100 mg	N
J3130	Injection, testosterone enanthate, up to 200 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7050	Infusion, normal saline solution, 250 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml = 1 unit)	N
J7030	Infusion, normal saline solution, 1000 cc	N

TABLE 41—PROPOSED HCPCS CODES TO WHICH THE CY 2015 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY—Continued

Proposed CY 2015 HCPCS code	Proposed CY 2015 long descriptor	Proposed CY 2015 SI
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	K
J8521	Capecitabine, oral, 500 mg	K
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

3. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. Most physician Part B drugs are paid at ASP+6 percent pursuant to section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.

It has been our longstanding policy to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In this CY 2015 OPPS/ASC proposed rule, we are proposing to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

Since CY 2006, we have attempted to establish a drug payment methodology that reflects hospitals' acquisition costs for drugs and biologicals while taking into account relevant pharmacy overhead and related handling expenses. We have attempted to collect more data on hospital overhead charges for drugs and biologicals by making several proposals that would require hospitals to change the way they report the cost and charges for drugs. None of these proposals were adopted due to significant stakeholder concern, including that hospitals stated that it would be administratively burdensome to report hospital overhead charges. We established a payment policy for separately payable drugs and biologicals, authorized by section 1833(t)(14)(A)(iii)(I) of the Act, based on an ASP+X amount that is calculated by comparing the estimated aggregate cost of separately payable drugs and biologicals in our claims data to the estimated aggregate ASP dollars for separately payable drugs and biologicals, using the ASP as a proxy for average acquisition cost (70 FR 68642 through 68643). We referred to this methodology as our standard drug payment methodology. Taking into consideration comments made by the pharmacy stakeholders and acknowledging the limitations of the reported data due to charge compression and hospitals' reporting practices, we added an ''overhead adjustment'' in CY 2010 (an internal adjustment of the data) by redistributing cost from coded and uncoded packaged drugs and biologicals to separately payable drugs in order to provide more appropriate payments for drugs and biologicals in the HOPD. We continued this methodology, and we further refined it in CY 2012 by finalizing a policy to update the redistribution amount for inflation and to keep the redistribution ration constant between the proposed rule and the final rule. For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with

comment period (77 FR 68383 through 68385).

Because of continuing uncertainty about the full cost of pharmacy overhead and acquisition cost, based in large part on the limitations of the submitted hospital charge and claims data for drugs, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386) we indicated our concern that the continued use of the standard drug payment methodology (including the overhead adjustment) still may not appropriately account for average acquisition and pharmacy overhead cost and, therefore, may result in payment rates that are not as predictable, accurate, or appropriate as they could be. Section 1833(t)(14)(A)(iii)(II) of the Act requires an alternative methodology for determining payment rates for SCODS wherein, if hospital acquisition cost data are not available, payment shall be equal (subject to any adjustment for overhead costs) to payment rates established under the methodology described in section 1842(o), 1847A, or 1847B of the Act. We refer to this alternative methodology as the ''statutory default.'' In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386), we noted that section 1833(t)(14)(A)(iii)(II) of the Act authorizes the Secretary to calculate and adjust, as necessary, the average price for a drug in the year established under section 1842(o), 1847A, or 1847B of the Act, as the case may be, in determining payment for SCODs. Pursuant to sections 1842(o) and 1847A of the Act, Part B drugs are paid at ASP+6 percent when furnished in physicians' offices. We indicated that we believe that establishing the payment rates based on the statutory default of ASP+6 percent is appropriate as it yields increased predictability in payment for separately payable drugs and biologicals under the OPPS and, therefore, we finalized our proposal for CY 2013 to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act, referred to as the statutory default. We also finalized our proposal that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals, that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals for CY 2013 (77 FR 68389).

b. Proposed CY 2015 Payment Policy

For CY 2015, we are proposing to continue our CY 2014 policy and pay for separately payable drugs and biologicals at ASP+6 percent pursuant to section 1833(t)(14)(A)(iii)(II) of the Act, referred to as the ''statutory default.'' We are proposing that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. We also are proposing that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals.

4. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in CY 2010 and continuing for CY 2014, we established a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through separately payable therapeutic radiopharmaceuticals in CY 2015. Therefore, we are proposing for CY 2015 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also are proposing to rely on CY 2013 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals, according to our usual process for updating the payment rates for separately payable drugs and biologicals, on a quarterly basis if updated ASP information is available. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

The proposed CY 2015 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

5. Proposed Payment for Blood Clotting Factors

For CY 2014, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee. That is, for CY 2014, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2014 updated furnishing fee was $0.192 per unit.

For CY 2015, we are proposing to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician office and inpatient hospital setting, and first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment

period (72 FR 66765), we are proposing to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

6. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) did not address the OPPS payment in CY 2005 and subsequent years for drugs, biologicals, and radiopharmaceuticals that have assigned HCPCS codes, but that do not have a reference AWP or approval for payment as pass-through drugs or biologicals. Because there was no statutory provision that dictated payment for such drugs, biologicals, and radiopharmaceuticals in CY 2005, and because we had no hospital claims data to use in establishing a payment rate for them, we investigated several payment options for CY 2005 and discussed them in detail in the CY 2005 OPPS final rule with comment period (69 FR 65797 through 65799).

For CYs 2005 to 2007, we implemented a policy to provide separate payment for new drugs, biologicals, and radiopharmaceuticals with HCPCS codes (specifically those new drug, biological, and radiopharmaceutical HCPCS codes in each of those calendar years that did not crosswalk to predecessor HCPCS codes) but which did not have pass-through status, at a rate that was equivalent to the payment they received in the physician's office setting, established in accordance with the ASP methodology for drugs and biologicals, and based on charges adjusted to cost for radiopharmaceuticals. Beginning in CY 2008 and continuing through CY 2014, we implemented a policy to provide payment for new drugs and biologicals with HCPCS codes (except those that are policy-packaged), but which did not have pass-through status and were without OPPS hospital claims data, at an amount consistent with the final OPPS payment methodology for other separately payable nonpass-through drugs and biologicals for the given year.

For CY 2015, we are proposing to continue this policy and provide payment for new drugs, biologicals, and therapeutic radiopharmaceuticals that do not have pass-through status at ASP+6 percent, consistent with the proposed CY 2015 payment methodology for other separately payable nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals, which is proposed to be ASP+6 percent. We believe this proposed policy would ensure that new nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, biologicals, and therapeutic radiopharmaceuticals under the OPPS.

For CY 2015, we also are proposing to package payment for all new nonpass-through policy-packaged products (diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) with HCPCS codes but without claims data (those new CY 2015 HCPCS codes that do not crosswalk to predecessor HCPCS codes). This is consistent with the proposed policy packaging of all existing nonpass-through diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in more detail in section II.A.3. of this proposed rule.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2015, we are proposing to continue our policy of using the WAC for the product to establish the initial payment rate for new nonpass-through drugs and biologicals with HCPCS codes, but which are without OPPS claims data. However, we note that if the WAC is also unavailable, we would make payment at 95 percent of the product's most recent AWP. We also are proposing to assign status indicator ''K'' (Separately paid nonpass-through drugs and biologicals, including therapeutic radiopharmaceuticals) to HCPCS codes for new drugs and biologicals without OPPS claims data and for which we have not granted pass-through status. With respect to new nonpass-through drugs and biologicals for which we do not have ASP data, we are proposing that once their ASP data become available in later quarterly submissions, their payment rates under the OPPS would be adjusted so that the rates would be based on the ASP methodology and set to the proposed ASP-based amount (proposed for CY 2015 at ASP+6 percent) for items that have not been granted pass-through status. This proposed policy, which utilizes the ASP methodology for new nonpass-through drugs and biologicals with an ASP, is consistent with prior years' policies for these items and would ensure that new nonpass-through drugs and biologicals would be treated like other drugs and biologicals under the OPPS, unless they are granted pass-through status.

Similarly, we are proposing to continue to base the initial payment for new therapeutic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals are not available. If the WACs are also unavailable, we are proposing to make payment for new therapeutic radiopharmaceuticals at 95 percent of the products' most recent AWP because we would not have mean costs from hospital claims data upon which to base payment. As we are proposing with new drugs and biologicals, we are proposing to continue our policy of assigning status indicator ''K'' to HCPCS codes for new therapeutic radiopharmaceuticals without OPPS claims data for which we have not granted pass-through status.

Consistent with other ASP-based payment, for CY 2015, we are proposing to announce any changes to the payment amounts for new drugs and biologicals in the CY 2015 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2015 if later quarter ASP submissions (or more recent WACs or AWPs) indicate that changes to the payment rates for these drugs and biologicals are necessary. The payment rates for new therapeutic radiopharmaceuticals also would be changed accordingly based on later quarter ASP submissions. We note that the new CY 2015 HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals were not available at the time of development of this proposed rule. However, these agents will be included in Addendum B to the CY 2015 OPPS/ASC final rule with comment period (which will be available via the Internet on the CMS Web site), where they will be assigned comment indicator ''NI.'' This comment indicator reflects that their interim final OPPS treatment will be open to public comment in the CY 2015 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2013 and/or CY 2014 for which we did not have CY 2013 hospital

claims data available for this proposed rule and for which there are no other HCPCS codes that describe different doses of the same drug, but which have pricing information available for the ASP methodology. In order to determine the packaging status of these products for CY 2015, we are proposing to continue our policy to calculate an estimate of the per day cost of each of these items by multiplying the payment rate of each product based on ASP+6 percent, similar to other nonpass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting. This rationale was first adopted in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68666 through 68667).

We are proposing to package items for which we estimated the per day administration cost to be less than or equal to $90 and to pay separately for items for which we estimated the per day administration cost to be greater than $90 (with the exception of diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure, which we are proposing to continue to package regardless of cost) in CY 2015. We also are proposing that the CY 2015 payment for separately payable items without CY 2013 claims data would be ASP+6 percent, similar to payment for other separately payable nonpass-through drugs and biologicals under the OPPS. In accordance with the ASP methodology paid in the physician's office setting, in the absence of ASP data, we are proposing to use the WAC for the product to establish the initial payment rate and, if the WAC is also unavailable, we would make payment at 95 percent of the most recent AWP available. The proposed estimated units per day and status indicators for these items are displayed in Table 42 of this proposed rule.

Finally, there are 35 drugs and biologicals, shown in Table 43 of this proposed rule that were payable in CY 2013 but for which we lacked CY 2013 claims data and any other pricing information for the ASP methodology for this proposed rule. For CY 2010, we finalized a policy to assign status indicator ''E'' (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) whenever we lacked claims data and pricing information and were unable to determine the per day cost of a drug or biological. In addition, we noted that we would provide separate payment for these drugs and biologicals if pricing information reflecting recent sales became available mid-year for the ASP methodology.

For CY 2015, as we finalized in CY 2014 (78 FR 75031), we are proposing to continue to assign status indicator ''E'' to drugs and biologicals that lack CY 2013 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2013 hospital claims data or data based on the ASP methodology that are assigned status indicator ''E'' on this basis at the time of this proposed rule for CY 2015 are displayed in Table 43 of this proposed rule. We also are proposing to continue our policy to assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2015 if pricing information becomes available.

TABLE 42—DRUGS AND BIOLOGICALS WITHOUT CY 2013 CLAIMS DATA

CY 2015 HCPCS Code	CY 2015 Long descriptor	Estimated average number of units per day	Proposed CY 2015 SI	Proposed CY 2015 APC
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1	K	1422
J0215	Injection, alefacept, 0.5 mg	29	K	1633
J0364	Injection, apomorphine hydrochloride, 1 mg	1	N	N/A
J0630	Injection, calcitonin salmon, up to 400 units	2	K	1433
J0638	Injection, canakinumab, 1 mg	180	K	1311
J3355	Injection, urofollitropin, 75 iu	2	K	1741
J7196	Injection, antithrombin recombinant, 50 i. U.	268	K	1332
J8650	Nabilone, oral, 1 mg	4	K	1424
J9151	Injection, daunorubicin citrate, liposomal formulation, 10 mg	10	K	0821
J9215	Injection, interferon, alfa-n3, (human leukocyte derived), 250,000 iu	1	N	N/A
J9300	Injection, gemtuzumab ozogamicin, 5 mg	1	K	9004

TABLE 43—DRUGS AND BIOLOGICALS WITHOUT CY 2013 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2015 HCPCS Code	CY 2015 Long descriptor	Proposed CY 2015 SI
90296	Diphtheria antitoxin, equine, any route	E
90393	Vaccina immune globulin, human, for intramuscular use	E
90477	Adenovirus vaccine, type 7, live, for oral use	E
90644	Meningococcal conjugate vaccine, serogroups c & y and hemophilus influenza b vaccine (hib-mency), 4 dose schedule, when administered to children 2–15 months of age, for intramuscular use.	E
90681	Rotavirus vaccine, human, attenuated, 2 dose schedule, live, for oral use	E
90727	Plague vaccine, for intramuscular use	E
J0190	Injection, biperiden lactate, per 5 mg	E
J0205	Injection, alglucerase, per 10 units	E
J0350	Injection, anistreplase, per 30 units	E
J0365	Injection, aprotonin, 10,000 kiu	E
J0395	Injection, arbutamine hcl, 1 mg	E

TABLE 43—DRUGS AND BIOLOGICALS WITHOUT CY 2013 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY—Continued

CY 2015 HCPCS Code	CY 2015 Long descriptor	Proposed CY 2015 SI
J0710	Injection, cephapirin sodium, up to 1 gm	E
J1180	Injection, dyphylline, up to 500 mg	E
J1435	Injection estrone per 1 MG	E
J1562	Injection, immune globulin (vivaglobin), 100 mg	E
J1620	Injection, gonadorelin hydrochloride, per 100 mcg	E
J1655	Injection, tinzaparin sodium, 1000 iu	E
J1730	Injection, diazoxide, up to 300 mg	E
J1835	Injection, itraconazole, 50 mg	E
J2460	Injection, oxytetracycline hcl, up to 50 mg	E
J2513	Injection, pentastarch, 10% solution, 100 ml	E
J2670	Injection, tolazoline hcl, up to 25 mg	E
J2725	Injection, protirelin, per 250 mcg	E
J2940	Injection, somatrem, 1 mg	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
J3365	Injection, iv, urokinase, 250,000 i.u. vial	E
J3400	Injection, triflupromazine hcl, up to 20 mg	E
J7505	Muromonab-cd3, parenteral, 5 mg	E
J7513	Daclizumab, parenteral, 25 mg	E
J8562	Fludarabine phosphate, oral, 10 mg	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
J9212	Injection, interferon alfacon-1, recombinant, 1 microgram	E
J9219	Leuprolide acetate implant, 65 mg	E
Q0174	Thiethylperazine maleate, 10 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an iv anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.	E
Q0515	Injection, sermorelin acetate, 1 microgram	E

VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2015 entails estimating spending for two groups of items. The first group of items consists of device categories that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2015. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2014 or beginning in CY 2015. The sum of the CY 2015 pass-through estimates for these two groups of device categories equals the total CY 2015 pass-through spending estimate for device categories with pass-through status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) is the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), for CY 2015, we are proposing to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. We also are proposing that, beginning in CY 2015, applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology. As a result of this proposal, we are proposing that the last skin substitute pass-through applications evaluated using the drugs and biologicals pass-through evaluation process would be those with an application deadline of September 1, 2014, and an earliest effective date of January 1, 2015. Therefore, in light of this proposal, we would change the December 1, 2014, pass-through application deadline (for an earliest effective date of April 1, 2015) for both drugs and biologicals and devices to January 15, 2015 in order to provide sufficient time for applicants to adjust to

the new policies and procedures in effect as of January 1, 2015. We refer readers to section V.B.2.d of this proposed rule for further discussion of our proposal to change the pass-through evaluation process for skin substitutes. If we finalize this proposal, beginning in CY 2015 and in future years we would include an estimate of any skin substitutes eligible for pass-through payment in our estimate of pass-through spending for devices. We refer readers to section V.B.2.d of this proposed rule for details of the proposal to apply the device pass-through evaluation process and payment methodology to skin substitutes and similar products for applications submitted on or after January 1.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. We note that the Part B drug CAP program has been postponed since CY 2009, and such a program has not been proposed to be reinstated for CY 2015. Because we are proposing to pay for most nonpass-through separately payable drugs and biologicals under the CY 2015 OPPS at ASP+6 percent, as we discussed in section V.B.3. of this proposed rule, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and biologicals, and because we are proposing to pay for CY 2015 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this proposed rule, our estimate of drug and biological pass-through payment for CY 2015 for this group of items is $0, as discussed below.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents, without pass-through status will always be packaged into payment for the associated procedures and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section II.A.3. of this proposed rule. We are proposing that all of these policy-packaged drugs and biologicals with pass-through status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2015. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through status approved prior to CY 2015 is not $0. In section V.A.4. of this proposed rule, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we are proposing to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we are proposing to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2015. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2014 or beginning in CY 2015. The sum of the CY 2015 pass-through estimates for these two groups of drugs and biologicals equals the total CY 2015 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Proposed Estimate of Pass-Through Spending

We are proposing to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2015, consistent with section 1833(t)(6)(E)(ii)(II) of the Act, and our OPPS policy from CY 2004 through CY 2014 (78 FR 75034 through 75036).

For the first group of devices for pass-through payment estimation purposes, there is one device category, HCPCS code C1841 (Retinal prosthesis, includes all internal and external components), eligible for pass-through payment as of October 1, 2013, continuing to be eligible for CY 2014, and that will continue to be eligible for pass-through payment for CY 2015. We estimate that CY 2015 pass-through expenditures for the first group of pass-through device categories to be $0.5 million. In estimating our CY 2015 pass-through spending for device categories in the second group, we include: Device categories that we knew at the time of the development of this proposed rule will be newly eligible for pass-through payment in CY 2015 (of which there are none); additional device categories that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2015; and contingent projections for new device categories established in the second through fourth quarters of CY 2015. We are proposing to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, the estimate of CY 2015 pass-through spending for this second group of device categories is $10.0 million.

To estimate CY 2015 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through status for CY 2015, we are proposing to utilize the most recent Medicare physician's office data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2015 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through status in CY 2015, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately

paid at ASP+6 percent, which is zero for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through status, we are proposing to include in the CY 2015 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment. For this proposed rule, using the proposed methodology described above, we calculated a CY 2015 proposed spending estimate for this first group of drugs and biologicals of approximately $2.8 million.

To estimate proposed CY 2015 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of this proposed rule are newly eligible for pass-through payment in CY 2015, additional drugs and biologicals that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2015, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2015), we are proposing to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2015 pass-through payment estimate. We also are proposing to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2015 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $2.2 million.

As discussed in section V.A. of this proposed rule, radiopharmaceuticals are considered drugs for pass-through payment purposes. Therefore, we include radiopharmaceuticals in our proposed CY 2015 pass-through spending estimate for drugs and biologicals. Our proposed CY 2015 estimate for total pass-through spending for drugs and biologicals (spending for the first group of drugs and biologicals ($2.8 million) plus spending for the second group of drugs and biologicals ($2.2 million)) equals $5.0 million.

In summary, in accordance with the methodology described above in this section, for this proposed rule, we estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2015 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2015 would be approximately $15.5 million (approximately $10.5 million for device categories and approximately $5.0 million for drugs and biologicals), which represents 0.03 percent of total projected OPPS payments for CY 2015. Therefore, we estimate that pass-through spending in CY 2015 would not amount to 2.0 percent of total projected OPPS CY 2015 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits

A. Proposed Payment for Hospital Outpatient Clinic and Emergency Department Visits

Since April 7, 2000, we have instructed hospitals to report facility resources for clinic and ED hospital outpatient visits using the CPT E/M codes and to develop internal hospital guidelines for reporting the appropriate visit level (65 FR 18451). Because a national set of hospital-specific codes and guidelines do not currently exist, we have advised hospitals that each hospital's internal guidelines that determine the levels of clinic and ED visits to be reported should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.

While many hospitals have advocated for hospital-specific national guidelines for visit billing since the OPPS started in 2000, and we have signaled in past rulemaking our intent to develop guidelines, this complex undertaking has proven challenging. Our work with interested stakeholders, such as hospital associations, along with a contractor, has confirmed that no single approach could consistently and accurately capture hospitals' relative costs. Public comments received on this issue, as well as our own knowledge of how clinics operate, have led us to conclude that it is not feasible to adopt a set of national guidelines for reporting hospital clinic visits that can accommodate the enormous variety of patient populations and service-mix provided by hospitals of all types and sizes throughout the country. Moreover, no single approach has been broadly endorsed by the stakeholder community.

After consideration of public comments we received on the CY 2014 OPPS/ASC proposed rule, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75045), we finalized a new policy which created an alphanumeric HCPCS code, G0463 (Hospital outpatient clinic visit for assessment and management of a patient), for hospital use only representing any and all clinic visits under the OPPS and assigned HCPCS code G0463 to new APC 0634. We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

In the CY 2014 OPPS/ASC final rule with comment period, we also stated our policy that we would continue to use our existing methodology to recognize the existing CPT codes for Type A ED visits as well as the five HCPCS codes that apply to Type B ED visits, and to establish the OPPS payment under our established standard process (78 FR 75036 through 75043). We refer readers to the CY 2014 OPPS/ASC final rule with comment period for a detailed discussion of the public comments and our rationale for the CY 2014 policies.

For CY 2015, we are proposing to continue the current policy, adopted in CY 2014, for clinic and ED visits. HCPCS code G0463 for hospital use only will represent any and all clinic visits under the OPPS. We are proposing to continue to assign HCPCS code G0463 to APC 0634. We are proposing to use CY 2013 claims data to develop the proposed CY 2015 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits currently recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). Finally, as we established in the CY 2014 OPPS/ASC final rule with comment period, there is no longer a policy to recognize a distinction between new and established patient clinic visits.

At the time of publication of the CY 2014 OPPS/ASC final rule with comment period, we stated that additional study was needed to fully assess the most suitable payment structure for ED visits, including the particular number of visit levels that would not underrepresent resources required to treat the most complex patients, such as trauma patients and that we believed it was best to delay any change in ED visit coding while we reevaluate the most appropriate payment structure for Type A and Type B ED visits (78 FR 75040). At this time, we continue to believe that additional study is needed to assess the most suitable payment structure for ED visits. We are not proposing any change in ED visit coding, but rather, for CY 2015, we are proposing to continue to use our existing methodology to recognize the existing CPT codes for Type A ED visits as well as the five HCPCS codes that apply to Type B ED visits, and to establish the CY 2015 proposed OPPS payment rates using our established standard process. We intend to further explore the issues described above related to ED visits, including concerns about excessively costly patients, such as trauma patients. We may propose changes to the coding and APC assignments for ED visits in future rulemaking.

B. Proposed Payment for Critical Care Services

For the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In the CY 2014 OPPS/ASC final rule with comment period, we continued to use the methodology established in the CY 2011 OPPS/ASC final rule with comment period for calculating a payment rate for critical care services that includes packaged payment of ancillary services, for example electrocardiograms, chest X-rays, and pulse oximetry. Critical care services are described by CPT codes 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and 99292 (Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)).

Compared to the CY 2012 hospital claims data used for the CY 2014 OPPS ratesetting, the CY 2013 hospital claims data used for the CY 2015 OPPS ratesetting again show increases in the geometric mean line item costs as well as the geometric mean line item charges for CPT code 99291, which continue to suggest that hospitals' billing practices for CPT code 99291 have remained the same. Because the CY 2013 claims data do not support any significant change in hospital billing practices for critical care services, we continue to believe that it would be inappropriate to pay separately the ancillary services that hospitals typically report in addition to CPT codes for critical care services. Therefore, for CY 2015, we are proposing to continue our policy (that has been in place since CY 2011) to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data. We also are proposing to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment. We will continue to monitor the hospital claims data for CPT code 99291 in order to determine whether revisions to this policy are warranted based on changes in hospitals' billing practices.

VIII. Proposed Payment for Partial Hospitalization Services

A. Background

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. Section 1861(ff)(1) of the Act defines partial hospitalization services as ''the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.'' Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a partial hospitalization program (PHP) is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC) (as defined in subparagraph (B)), and ''which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting.'' Section 1861(ff)(3)(B) of the Act defines a community mental health center for purposes of this benefit.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the OPD services to be covered under the OPPS. The Medicare regulations that implement this provision specify, under 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

Section 1833(t)(2)(C) of the Act, in pertinent part, requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs'' using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, subparagraph (B) provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we have developed the PHP APCs. Section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.''

Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs have been used to calculate the relative payment weights for PHP APCs.

From CY 2003 through CY 2006, the median per diem costs for CMHCs fluctuated significantly from year to year, while the median per diem costs for hospital-based PHPs remained relatively constant. We were concerned that CMHCs may have increased and decreased their charges in response to Medicare payment policies. Therefore, we began efforts to strengthen the PHP

benefit through extensive data analysis and policy and payment changes finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). We made two refinements to the methodology for computing the PHP median: The first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill. We refer readers to a complete discussion of these refinements in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676).

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tiered payment approach for PHP services under which we paid one amount for days with 3 services (APC 0172 Level I Partial Hospitalization) and a higher amount for days with 4 or more services (APC 0173 Level II Partial Hospitalization). We refer readers to section X.B. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68693) for a full discussion of the two-tiered payment system. In addition, for CY 2009, we finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694).

Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). These changes have helped to strengthen the PHP benefit. We also revised the partial hospitalization benefit to include several coding updates. We refer readers to section X.C.3. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68695 through 68697) for a full discussion of these requirements.

For CY 2010, we retained the two-tiered payment approach for PHP services and used only hospital-based PHP data in computing the APC per diem payment rates. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In CY 2011, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care ''other than in an individual's home or in an inpatient or residential setting.'' In addition, in accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth under section 1861(ff)(3)(B) of the Act. We discussed our finalized policies for these two provisions of HCERA 2010 in section X.C. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71990).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we also established four separate PHP APC per diem payment rates, two for CMHCs (for Level I and Level II services) and two for hospital-based PHPs (for Level I and Level II services), based on each provider's own unique data. As stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46300) and the final rule with comment period (75 FR 71991), for CY 2011, using CY 2009 claims data, CMHC costs had significantly decreased again. We attributed the decrease to the lower cost structure of CMHCs compared to hospital-based PHP providers, and not the impact of the CY 2009 policies. CMHCs have a lower cost structure than hospital-based PHP providers, in part, because the data showed that CMHCs generally provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. Therefore, it was inappropriate to continue to treat CMHCs and hospital-based providers in the same manner regarding payment, particularly in light of such disparate differences in costs. We also were concerned that paying hospital-based PHPs at a lower rate than their cost structure reflects could lead to hospital-based PHP closures and possible access problems for Medicare beneficiaries because hospital-based PHPs are located throughout the country and, therefore, offer the widest access to PHP services. Creating the four payment rates (two for CMHCs and two for hospital-based PHPs) based on each provider's data supported continued access to the PHP benefit, while also providing appropriate payment based on the unique cost structures of CMHCs and hospital-based PHPs. In addition, separation of data by provider type was supported by several hospital-based PHP commenters who responded to the CY 2011 OPPS/ASC proposed rule (75 FR 71992).

For CY 2011, we instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates based solely on CMHC data. For CY 2011, under the transition methodology, CMHC PHP APCs Level I and Level II per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP median costs and the CY 2011 final CMHC median and then adding that number to the CY 2011 final CMHC median. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for PHP services based on each provider type's data, while at the same time allowing providers time to adjust their business operations and protect access to care for beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and, based on these analyses, we might further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion.

After publication of the CY 2011 OPPS/ASC final rule with comment period, a CMHC and one of its patients filed an application for a preliminary injunction, challenging the OPPS payment rates for PHP services provided by CMHCs in CY 2011 as adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71995). We refer readers to the court case, *Paladin Cmty. Mental Health Ctr.* v. *Sebelius,* 2011 WL 3102049 (W.D.Tex. 2011), *aff'd,* 684 F.3d 527 (5th Cir. 2012) (*Paladin*). The plaintiffs in the *Paladin* case challenged the agency's use of cost data derived from both hospitals and CMHCs in determining the relative payment weights for the OPPS payment rates for PHP services furnished by CMHCs, alleging that section 1833(t)(2)(C) of the Act requires that such relative payment weights be based on cost data derived solely from hospitals. As discussed above, section 1833(t)(2)(C) of the Act requires CMS to ''establish relative payment weights for covered OPD services (and any groups of such services . . .) . . . based on . . . hospital costs.'' Numerous courts have held that ''based on'' does not mean ''based exclusively on.'' On July 25, 2011, the District Court dismissed the plaintiffs' complaint and application for a preliminary injunction for lack of subject-matter jurisdiction, which the plaintiffs appealed to the United States

Court of Appeals for the Fifth Circuit. On June 15, 2012, the Court of Appeals affirmed the District Court's dismissal for lack of subject-matter jurisdiction and found that the Secretary's payment rate determinations for PHP services are not a facial violation of a clear statutory mandate (*Paladin,* 684 F.3d at 533).

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for PHP services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for hospital-based PHP services based exclusively on hospital data. The statute is reasonably interpreted to allow the relative payment weights for the OPPS payment rates for PHP services provided by CMHCs to be based solely on CMHC data and relative payment weights for hospital-based PHP services to be based exclusively on hospital data. Section 1833(t)(2)(C) of the Act requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on . . . hospital costs.'' In pertinent part, subparagraph (B) provides that ''the Secretary may establish groups of covered OPD services . . . so that services classified within each group are comparable clinically and with respect to the use of resources.'' In accordance with subparagraph (B), we developed the PHP APCs, as set forth in § 419.31 of the regulations (65 FR 18446 and 18447; 63 FR 47559 through 47562 and 47567 through 47569). As discussed above, PHP services are grouped into APCs.

Based on section 1833(t)(2)(C) of the Act, we believe that the word ''establish'' can be interpreted as applying to APCs at the inception of the OPPS in 2000 or whenever a new APC is added to the OPPS. In creating the original APC for PHP services (APC 0033), we did ''establish'' the initial relative payment weight for PHP services, provided in both hospital-based and CMHC-based settings, only on the basis of hospital data. Subsequently, from CY 2003 through CY 2008, the relative payment weights for PHP services were based on a combination of hospital and CMHC data. For CY 2009, we established new APCs for PHP services based exclusively on hospital data. Specifically, we adopted a two-tiered APC methodology (in lieu of the original APC 0033) under which CMS paid one rate for days with 3 services (APC 0172) and a different payment rate for days with 4 or more services (APC 0173). These two new APCs were established using only hospital data. For CY 2011, we added two new APCs (APCs 0175 and 0176) for PHP services provided by hospitals and based the relative payment weights for these APCs solely on hospital data. APCs 0172 and 0173 were designated for PHP services provided by CMHCs and were based on a mixture of hospital and CMHC data. As the Secretary argued in the *Paladin* case, the courts have consistently held that the phrase ''based on'' does not mean ''based exclusively on.'' Thus, the relative payment weights for the two APCs for PHP services provided by CMHCs in CY 2011 were ''based on'' hospital data, no less than the relative payment weights for the two APCs for hospital-based PHP services.

Although we used hospital data to establish the relative payment weights for APCs 0033, 0172, 0173, 0175, and 0176 for PHP services, we believe that we have the authority to discontinue the use of hospital data in determining the OPPS relative payment weights for PHP services provided by CMHCs. Other parts of section 1833(t)(2)(C) of the Act make plain that the data source for the relative payment weights is subject to change from one period to another. Section 1833(t)(2)(C) of the Act provides that, in establishing the relative payment weights, ''the Secretary shall [ ] us[e] data on claims from 1996 and us[e] data from the most recent available cost reports.'' We used 1996 data (in addition to 1997 data) in determining only the original relative payment weights for 2000. In the ensuing calendar year updates, we continually used more recent cost report data.

Moreover, section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.'' For purposes of the CY 2012 update, we exercised our authority under section 1833(t)(9)(A) of the Act to change the data source for the relative payment weights for PHP services provided by CMHCs based on ''new cost data, and other relevant information and factors.''

In the CY 2014 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs, on geometric means rather than on the medians. For CY 2014, we established the four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims data for each provider type. We refer readers to the CY 2014 OPPS/ASC final rule with comment period for a more detailed discussion (78 FR 75047 through 75050).

B. Proposed PHP APC Update for CY 2015

For CY 2015, we are proposing to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. We computed proposed CMHC PHP APC geometric mean per diem costs for Level I (3 services per day) and Level II (4 or more services per day) PHP services using only CY 2013 CMHC claims data, and proposed hospital-based PHP APC geometric mean per diem costs for Level I and Level II PHP services using only CY 2013 hospital-based PHP claims data. These proposed geometric mean per diem costs are shown in Table 44 below.

TABLE 44—PROPOSED CY 2015 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2013 CLAIMS DATA

APC	Group title	Proposed geometric mean per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$97.43
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	114.93
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	177.32
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	190.21

For CY 2015, the proposed geometric mean per diem costs for days with 3 services (Level I) is approximately $97 for CMHCs and approximately $177 for hospital-based PHPs. The proposed geometric mean per diem costs for days with 4 or more services (Level II) is approximately $115 for CMHCs and approximately $190 for hospital-based PHPs.

The CY 2015 proposed geometric mean per diem costs for CMHCs calculated under the proposed CY 2015 methodology using CY 2013 claims data have remained relatively constant when compared to the CY 2014 final geometric mean per diem costs for CMHCs established in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75050), with geometric mean per diem costs for Level I CMHC PHP services decreasing from approximately $99 to approximately $97 for CY 2015, and geometric mean per diem costs for Level II CMHC PHP services increasing from approximately $112 to approximately $115 for CY 2015.

The CY 2015 proposed geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2015 methodology using CY 2013 claims data show more variation when compared to the CY 2014 final geometric mean per diem costs for hospital-based PHPs, with geometric mean per diem costs for Level I hospital-based PHP services decreasing from approximately $191 to approximately $177 for CY 2015, and geometric mean per diem costs for Level II hospital-based PHP services decreasing from approximately $214 to approximately $190 for CY 2015.

We understand that having little variation in the PHP per diem payment amounts from one year to the next allows providers to more easily plan their fiscal needs. However, we believe that it is important to base the PHP payment rates on the claims and cost reports submitted by each provider type so these rates accurately reflect the cost information for these providers. We recognize that several factors may cause a fluctuation in the per diem payment amounts, including direct changes to the PHP APC per diem payment rate (for example, establishing separate APCs and associated per diem payment rates for CMHCs and hospital-based providers based on the provider type's costs), changes to the OPPS (for example, basing the relative payment weights on geometric mean costs), and provider-driven changes (for example, a provider's decision to change its mix of services or to change its charges and clinical practice for some services). We refer readers to a more complete discussion of this issue in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75049). We are inviting public comments on what causes PHP costs to fluctuate from year to year.

The proposed CY 2015 geometric mean per diem costs for the CMHC and hospital-based PHP APCs are shown in Table 44 of this proposed rule. We are inviting public comments on these proposals.

C. Proposed Separate Threshold for Outlier Payments to CMHCs

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), after examining the costs, charges, and outlier payments for CMHCs, we believed that establishing a separate OPPS outlier policy for CMHCs would be appropriate. A CMHC-specific outlier policy would direct OPPS outlier payments towards genuine cost of outlier cases, and address situations where charges were being artificially increased to enhance outlier payments. We created a separate outlier policy that would be specific to the estimated costs and OPPS payments provided to CMHCs. We note that, in the CY 2009 OPPS/ASC final rule with comment period, we established an outlier reconciliation policy to comprehensively address charging aberrations related to OPPS outlier payments (73 FR 68594 through 68599). Therefore, beginning in CY 2004, we designated a portion of the estimated OPPS outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

The separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004, and $0.5 million in outlier payments to CMHCs in CY 2005. In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments. We believe that this difference in outlier payments indicates that the separate outlier threshold for CMHCs has been successful in keeping outlier payments to CMHCs in line with the percentage of OPPS payments made to CMHCs.

We are proposing to continue designating a portion of the estimated 1.0 percent outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS in CY 2015, excluding outlier payments. CMHCs are projected to receive 0.03 percent of total OPPS payments in CY 2015, excluding outlier payments. Therefore, we are proposing to designate 0.47 percent of the estimated 1.0 percent outlier target amount for CMHCs, and establish a threshold to achieve that level of outlier payments. Based on our simulations of CMHC payments for CY 2015, we are proposing to continue to set the threshold for CY 2015 at 3.40 times the highest CMHC PHP APC payment rate (that is, APC 0173 (Level II Partial Hospitalization)). We continue to believe that this approach would neutralize the impact of inflated CMHC charges on outlier payments and better target outlier payments to those truly exceptionally high-cost cases that might otherwise limit beneficiary access. In addition, we are proposing to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2015, we are proposing to continue to pay 50 percent of CMHC per diem costs over the threshold. In section II.G. of this proposed rule, for the hospital outpatient outlier payment policy, we are proposing to set a dollar threshold in addition to an APC multiplier threshold. Because the PHP APCs are the only APCs for which CMHCs may receive payment under the OPPS, we would not expect to redirect outlier payments by imposing a dollar threshold. Therefore, we are not proposing to set a dollar threshold for CMHC outlier payments.

In summary, we are proposing to establish that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. We are inviting public comments on these proposals.

IX. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient list) and, therefore, will not be paid by Medicare under the OPPS; and on the criteria that we use to review the inpatient list each year to determine whether or not any procedures should be removed from the list.

B. Proposed Changes to the Inpatient List

For the CY 2015 OPPS, we are proposing to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65835)) of reviewing the current list of procedures on the inpatient list to identify any procedures that may be removed from the list. The established criteria upon which we make such a determination are as follows:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that we have already removed from the inpatient list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

Using this methodology, we did not identify any procedures that potentially could be removed from the inpatient list for CY 2015. Therefore, we are proposing to not remove any procedures from the inpatient list for CY 2015.

After our annual review of APCs and code assignments as required by section 1833(t)(9) of the Act and further clinical review performed by CMS medical officers, we are proposing to add CPT code 22222 (Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic) to the CY 2015 inpatient list.

The complete list of codes that we are proposing to be paid by Medicare in CY 2015 only as inpatient procedures is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

X. Proposed Nonrecurring Policy Changes: Collecting Data on Services Furnished in Off-Campus Provider-Based Departments

As we discussed in the CY 2014 OPPS/ASC proposed rule and final rule with comment period (78 FR 43626 and 78 FR 75061, respectively) and in the CY 2014 Medicare Physician Fee Schedule (MPFS) proposed rule (78 FR 43301 and 78 FR 74427), in recent years, the research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of physicians' services in a hospital setting. When a Medicare beneficiary receives outpatient services in a hospital, the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physician's office.

We continue to seek a better understanding of how the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments affects payments under the MPFS and OPPS, as well as beneficiary cost-sharing obligations. MedPAC continues to question the appropriateness of increased Medicare payment and beneficiary cost-sharing when physician offices become hospital outpatient departments and to recommend that Medicare pay selected hospital outpatient services at MPFS rates (MedPAC March 2012 and June 2013 *Report to Congress*). In order to understand how this trend is affecting Medicare, we need information on the extent to which this shift is occurring. To that end, during the CY 2014 OPPS/ASC rulemaking cycle, we sought public comment regarding the best method for collecting information and data that would allow us to analyze the frequency, type, and payment for physicians' and outpatient hospital services furnished in off-campus provider-based hospital outpatient departments (78 FR 75061 through 75062 and 78 FR 74427 through 74428). In response to our solicitation, we received many detailed public comments. However, the commenters did not present a consensus opinion regarding the options we presented in last year's proposed rule. Based on our analysis of the public comments we received, we believe the most efficient and equitable means of gathering this important information across two different payment systems would be to create a HCPCS modifier to be reported with every code for physicians' services and outpatient hospital services furnished in an off-campus provider-based department of a hospital on both the CMS–1500 claim form for physicians' services and the UB–04 form (CMS Form 1450) for hospital outpatient services. We note that a main provider may treat an off-campus facility as provider-based if certain requirements in 42 CFR 413.65 are satisfied, and we define a ''campus'' at 42 CFR 413.65(a)(2) to be the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

Section 220(a) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) added a new subparagraph (M) under section 1848(c)(2) of the Act that granted CMS the authority to engage in data collection to support valuation of services paid under the MPFS. We are seeking more information on the frequency and type of services furnished in provider-based departments under this authority to improve the accuracy of MPFS practice expense payments for services furnished in off-campus provider-based departments. We discuss this issue in more detail in the CY 2015 MPFS proposed rule (CMS–1612–P). In that discussion, we note our concerns that our current MPFS practice expense methodology primarily distinguishes between the resources involved in furnishing services in two sites of service: The nonfacility setting and the facility setting. As more physician practices become hospital-based and are treated as off-campus provider-based departments, we believe it is important to develop an understanding of which practice expense costs typically are incurred by the physicians and practitioners in the setting, which are incurred by the hospital, and whether the facility and nonfacility site of service differentials adequately account for the typical resource costs given these new ownership arrangements.

To understand how this trend is affecting Medicare, including the accuracy of payments made through the MPFS, we need to develop data to assess the extent to which this shift toward hospital-based physician practices is occurring. Therefore, we are proposing to collect information on the type and frequency of physicians' services and outpatient hospital services furnished in off-campus provider-based departments beginning January 1, 2015, in accordance with our authority under section 1834(c)(2)(M) of the Act (as added by section 220(a) of Pub. L. 113–93). As noted above, we would create a HCPCS modifier that is to be reported with every code for physicians' services and outpatient hospital services furnished in an off-campus provider-based department of a hospital. The modifier would be reported on both the CMS–1500 claim form for physicians' services and the UB–04 form (CMS Form 1450) for hospital outpatient services. We are seeking additional public comment on whether or not the

use of a modifier code is the best mechanism for collecting this service-level data in the hospital outpatient department.

XI. Proposed CY 2015 OPPS Payment Status and Comment Indicators

A. Proposed CY 2015 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The complete list of the proposed CY 2015 payment status indicators and their definitions is displayed in Addendum D1 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The proposed CY 2015 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The proposed changes to CY 2015 payment status indicators and their definitions are discussed in detail below.

We note that in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74869 through 74888), for CY 2014, we created a new status indicator ''J1'' to identify HCPCS codes that are paid under a comprehensive APC. However, because we delayed implementation of the new comprehensive APC policy until CY 2015, we also delayed the effective date of payment status indicator ''J1'' to CY 2015. A claim with payment status indicator ''J1'' will trigger a comprehensive APC payment for the claim. We refer readers to section II.A.2.e. of this proposed rule for a discussion of implementation of the new comprehensive APC policy.

For CY 2015, we are proposing to delete payment status indicator ''X,'' and assign ancillary services that are currently assigned payment status indicator ''X'' to either payment status indicator ''Q1'' or ''S.'' We also are proposing to revise the definition payment status indicator ''Q1'' by removing payment status indicator ''X'' from the packaging criteria, so that codes assigned payment status indicator ''Q1'' would be designated as STV-packaged, rather than STVX-packaged because payment status indicator ''X'' is proposed for deletion. These proposed changes are discussed in greater detail in section II.A.3.c.(1) of this proposed rule.

In addition, for CY 2015, we are proposing to clarify the definition of payment status indicator ''E'' to state that status indicator ''E'' applies to items, codes, and services—

- For which pricing is not available;
- Not covered by any Medicare outpatient benefit category;
- Statutorily excluded by Medicare; and
- Not reasonable and necessary.

Regarding items ''for which pricing is not available,'' this applies to drugs and biologicals assigned a HCPCS code but with no available pricing information, for example, WAC.

In reviewing the OPPS status indicators and Addendum D1 for CY 2015, we noticed that there are a few drugs or biologicals that are currently assigned payment status indicator ''A'' indicating payment under a non-OPPS fee schedule. These drugs are administered infrequently in conjunction with emergency dialysis for patients with ESRD, but when administered in the HOPD, they would be paid under the standard OPPS drug payment methodology for drugs and biologicals, that is, at ASP+6 percent unless they are packaged. We refer readers to section V. of this proposed rule for additional discussion of these drugs and their status indicators. Based on this proposed change to the status indicators for these drugs, for CY 2015, we are proposing to remove the phrase ''EPO for ESRD Patients'' from the list of examples for status indicator ''A.'' In addition, we are proposing to clarify the definition of payment status indicator ''A'' by adding the phrase ''separately payable'' to nonimplantable prosthetic and orthotic devices.

B. Proposed CY 2015 Comment Indicator Definitions

For the CY 2015 OPPS, we are proposing to use the same two comment indicators that are in effect for the CY 2014 OPPS.

- ''CH''—Active HCPCS codes in current and next calendar year; status indicator and/or APC assignment have changed or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

We are proposing to use the ''CH'' comment indicator in this CY 2015 OPPS/ASC proposed rule to indicate HCPCS codes for which the status indicator or APC assignment, or both, are proposed for change in CY 2015 compared to their assignment as of June 30, 2014. We believe that using the ''CH'' indicator in this proposed rule will facilitate the public's review of the changes that we are proposing for CY 2015. Use of the comment indicator ''CH'' in association with a composite APC indicates that the configuration of the composite APC is proposed to be changed in the CY 2015 OPPS/ASC final rule with comment period.

We are proposing to use the ''CH'' comment indicator in the CY 2015 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, would change in CY 2015 compared to their assignment as of December 31, 2014.

In addition, we are proposing that any existing HCPCS codes with substantial revisions to the code descriptors for CY 2015 compared to the CY 2014 descriptors would be labeled with comment indicator ''NI'' in Addendum B to the CY 2015 OPPS/ASC final rule with comment period. However, in order to receive the comment indicator ''NI,'' the CY 2015 revision to the code descriptor (compared to the CY 2014 descriptor) must be significant such that the new code descriptor describes a new service or procedure for which the OPPS treatment may change. We use comment indicator ''NI'' to indicate that these HCPCS codes will be open for comment as part of this CY 2015 OPPS/ASC final rule with comment period. Like all codes labeled with comment indicator ''NI,'' we will respond to public comments and finalize their OPPS treatment in the CY 2016 OPPS/ASC final rule with comment period.

In accordance with our usual practice, we are proposing that CPT and Level II HCPCS codes that are new for CY 2015 also would be labeled with comment indicator ''NI'' in Addendum B to the CY 2015 OPPS/ASC final rule with comment period.

Only HCPCS codes with comment indicator ''NI'' in the CY 2015 OPPS/ASC final rule with comment period are subject to comment. HCPCS codes that do not appear with comment indicator ''NI'' in the CY 2015 OPPS/ASC final rule with comment period will not be open to public comment, unless we specifically request additional comments elsewhere in the final rule with comment period.

We believe that the CY 2014 definitions of the OPPS comment

indicators continue to be appropriate for CY 2015. Therefore, we are proposing to continue to use those definitions without modification for CY 2015. The proposed definitions of the OPPS comment indicators are listed in Addendum D2 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

XII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to ASCs, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74378 through 74379), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68434 through 68467), and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75064 through 75090).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under § 416.2 and § 416.166 of the regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and that would not be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate to be furnished to Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to ASC covered surgical procedures (72 FR 42478).

In the August 2, 2007 final rule, we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. These covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment (72 FR 42495). Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). In addition, as discussed in detail in section XII.B. of this proposed rule, because we base ASC payment policies for covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, we also provide quarterly update change requests (CRs) for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). CMS releases new Level II codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. Thus, these quarterly updates are to implement newly created Level II HCPCS and Category III CPT codes for ASC payment and to update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New Category I CPT codes, except vaccine codes, are released only once a year and, therefore, are implemented only through the January quarterly update. New Category I CPT vaccine codes are released twice a year and, therefore, are implemented through the January and July quarterly updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for the process used to update the HCPCS and CPT codes (76 FR 42291).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new procedures, and procedures for which there is revised coding, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

B. Proposed Treatment of New Codes

1. Proposed Process for Recognizing New Category I and Category III CPT Codes and Level II HCPCS Codes

Category I CPT, Category III CPT, and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims: (1) Category I CPT codes, which describe surgical procedures and vaccine codes; (2) Category III CPT codes, which describe new and emerging technologies, services, and procedures; and (3) Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule to evaluate each year all new Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures (72 FR 42533 through 42535). In addition, we identify new codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system.

We have separated our discussion below into two sections based on whether we are proposing to solicit public comments in this CY 2015 OPPS/ASC proposed rule (and respond to those comments in the CY 2015 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2015 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2016 OPPS/ASC final rule with comment period).

We note that we sought public comment in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75067) on the new Category I and Category III CPT and Level II HCPCS codes that were effective January 1, 2014. We also sought public comment in the CY 2014 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2013. These new codes, with an effective date of October 1, 2013, or January 1, 2014, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2014 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2014 OPPS/ASC final rule with comment period. We will respond to public comments and finalize the treatment of these codes under the ASC payment system in the CY 2015 OPPS/ASC final rule with comment period.

2. Proposed Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April 2014 and July 2014 for Which We Are Soliciting Public Comments in This Proposed Rule

In the April 2014 and July 2014 CRs, we made effective for April 1, 2014 and July 1, 2014, respectively, a total of seven new Level II HCPCS codes and four new Category III CPT codes that describe ASC covered surgical procedures and covered ancillary services that were not addressed in the CY 2014 OPPS/ASC final rule with comment period.

In the April 2014 ASC quarterly update (Transmittal 2927, CR 8675, dated April 10, 2014), we added two new surgical Level II HCPCS codes and one new drug and biological Level II HCPCS code to the list of covered surgical procedures and covered ancillary services, respectively. Table 45 below lists the new Level II HCPCS codes that were implemented April 1, 2014, along with their proposed payment indicators for CY 2015.

In the July 2014 quarterly update (Transmittal 2970, CR 8786, dated May 23, 2014), we added one new brachytherapy Level II HCPCS code and three new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 46 below lists the new Level II HCPCS codes that were implemented July 1, 2014 along with their proposed payment indicators and proposed ASC payment rates for CY 2015.

Through the July 2014 quarterly update CR, we also implemented ASC payment for four new Category III CPT codes as one ASC covered surgical procedure and three covered ancillary services, effective July 1, 2014. These codes are listed in Table 47 below, along with their proposed payment indicators and proposed payment rates for CY 2015.

The HCPCS codes listed in Table 45 are included in Addenda AA or BB to this proposed rule (which are available via the Internet on the CMS Web site). Because the payment rates associated with the new Level II HCPCS codes and Category III CPT codes that became effective July 1, 2014 (listed in Table 46 and Table 47 of this proposed rule) are not available to us in time for incorporation into the Addenda to this OPPS/ASC proposed rule, our policy is to include these HCPCS codes and their proposed payment indicators and payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes and their final payment indicators and rates will be included in the appropriate Addendum to the CY 2015 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2014 ASC quarterly update CR and their proposed CY 2015 payment indicators and rates that are displayed in Table 46 and Table 47 are not included in Addenda AA or BB to this proposed rule (which are available via the Internet on the CMS Web site). The final list of ASC covered surgical procedures and covered ancillary services and the associated payment weights and payment indicators will be included in Addenda AA or BB to the CY 2015 OPPS/ASC final rule with comment period, consistent with our annual update policy.

We invite public comment on these proposed payment indicators and the proposed payment rates for the new Category III CPT code and Level II HCPCS codes that were newly recognized as ASC covered surgical procedures or covered ancillary services in April 2014 and July 2014 through the quarterly update CRs, as listed in Tables 45, 46, and 47 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2015 OPPS/ASC final rule with comment period.

TABLE 45—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2014

CY 2014 HCPCS Code	CY 2014 Long descriptor	Proposed CY 2015 payment indicator
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants	G2
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants	G2
C9021	Injection, obinutuzumab, 10 mg	K2

G2 = Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.
K2 = Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate.

TABLE 46—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2014

CY 2014 HCPCS Code	CY 2014 Long descriptor	Proposed CY 2015 payment indicator	Proposed CY 2015 payment rate
C2644	Brachytherapy source, cesium-131 chloride solution, per millicurie	H2	$18.97
C9022	Injection, elosulfase alfa, 1mg	K2	226.42
C9134	Factor XIII (antihemophilic factor, recombinant), Tretten, per 10 i.u.	K2	14.10

TABLE 46—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2014—Continued

CY 2014 HCPCS Code	CY 2014 Long descriptor	Proposed CY 2015 payment indicator	Proposed CY 2015 payment rate
Q9970*	Injection, ferric carboxymaltose, 1 mg	K2	1.06

*HCPCS code Q9970 replaces HCPCS code C9441 effective July 1, 2014.
H2 = Brachytherapy source paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate.
K2 = Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate.

TABLE 47—NEW CATEGORY III CPT CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2014

CY 2014 CPT Code	CY 2014 Long descriptor	Proposed CY 2015 payment indicator	Proposed CY 2015 payment rate
0348T	Radiologic examination, radiostereometric analysis (RSA); spine, (includes, cervical, thoracic and lumbosacral, when performed).	Z2	$50.21
0349T	Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow and wrist, when performed).	Z2	$50.21
0350T	Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies), (includes hip, proximal femur, knee and ankle, when performed).	Z2	50.21
0356T	Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each.	R2	42.81

R2 = Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight.
Z2 = Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs.

3. Proposed Process for New Level II HCPCS Codes and Category I and Category III CPT Codes for Which We Will Be Soliciting Public Comments in the CY 2015 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and Category III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January ASC quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October ASC quarterly update CRs and incorporated these new codes in the final rule with comment period updating the ASC payment system for the following calendar year. All of these codes are flagged with comment indicator ''NI'' in Addenda AA and BB to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. The payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update.

We are proposing to continue this process for CY 2015. Specifically, for CY 2015, we are proposing to include in Addenda AA and BB to the CY 2015 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2015, that would be incorporated in the January 2015 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2014 or January 1, 2015, that would be released by CMS in its October 2014 and January 2015 ASC quarterly update CRs. These codes would be flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2015 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim payment status. Their payment indicators and payment rates, if applicable, would be open to public comment in the CY 2015 OPPS/ASC final rule with comment period and would be finalized in the CY 2016 OPPS/ASC final rule with comment period.

C. Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Additions to the List of ASC Covered Surgical Procedures

We are proposing to update the list of ASC covered surgical procedures by adding 10 procedures to the list for CY 2015. These 10 procedures were among those excluded from the ASC list for CY 2014 because we believed they did not meet the definition of a covered surgical procedure based on our expectation that they would pose a significant safety risk to Medicare beneficiaries or would require an overnight stay if performed in ASCs. We conducted a review of all HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. We determined that these 10 procedures could be safely performed in the ASC setting and would not require an overnight stay if performed in an ASC and, therefore, we are proposing to include them on the list of ASC covered surgical procedures for CY 2015.

The 10 procedures that we are proposing to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2015 payment indicators, are displayed in Table 48 below.

TABLE 48—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2015

CY 2014 HCPCS Code	CY 2014 Long descriptor	Proposed CY 2015 ASC payment indicator
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2.	G2
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below c2.	G2
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed).	G2
22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (list separately in addition to code for primary procedure).	N1
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical.	G2
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar.	G2
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar.	G2
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical.	G2
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar.	G2
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (eg, far lateral herniated intervertebral disc).	G2

b. Proposed Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated it would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the list of surgical procedures eligible for payment in ASCs, each year we identify surgical procedures as either temporarily office-based (these are new procedure codes without utilization data which our Medical Officers have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or non-office-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2015 to Covered Surgical Procedures Designated as Office-Based

In developing this proposed rule, we followed our policy to annually review and update the surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2013 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator ''G2'' (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2014, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2*,'' ''P3*,'' or ''R2*'' in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75071 through 75075).

Our review of the CY 2013 volume and utilization data resulted in our identification of two covered surgical procedures that we believe meet the criteria for designation as office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices and that our medical advisors believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The two CPT codes we are proposing to permanently designate as office-based are listed in Table 49 below.

TABLE 49—ASC COVERED SURGICAL PROCEDURES NEWLY PROPOSED FOR PERMANENT OFFICE-BASED DESIGNATION FOR CY 2015

CY 2014 CPT Code	CY 2014 Long descriptor	CY 2014 ASC payment indicator	Proposed CY 2015 ASC payment indicator *
10022	Fine needle aspiration; with imaging guidance	G2	P3
19296	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy.	G2	P2

* Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. According to the statutory formula, current law requires a negative update to the MPFS payment rates for CY 2015. For a discussion of those rates, we refer readers to the CY 2015 MPFS proposed rule.

We invite public comment on this proposal.

We also reviewed CY 2013 volume and utilization data and other information for the 8 procedures finalized for temporary office-based status in Table 52 and Table 53 in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75074 through 75075). Among these 8 procedures, there were very few claims data or no claims data for six procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound); CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies); CPT code 10030 (Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity, abdominal wall, neck), percutaneous); CPT code 64617 (Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we are proposing to maintain their temporary office-based designations for CY 2015.

We are proposing that one procedure that has a temporary office-based designation for CY 2014, CPT code 0226T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed), be packaged under the OPPS for CY 2015. Our policy is to package covered surgical procedures under the ASC payment system if these procedures are packaged under the OPPS. Consequently, we are proposing to package, and assign payment indicator ''N1'' to, this covered surgical procedure code in CY 2015.

HCPCS code 0124T (Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)) was finalized for temporary office-based status in the CY 2014 OPPS/ASC final rule with comment period; however, this code was deleted effective December 31, 2013.

The proposed CY 2015 payment indicator designations for the 7 remaining procedures that were temporarily designated as office-based in CY 2014 are displayed in Table 50 below. The procedures for which the proposed office-based designations for CY 2015 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 50—PROPOSED CY 2015 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2014 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2014 CPT Code	CY 2014 Long descriptor	CY 2014 ASC Payment indicator	Proposed CY 2015 ASC payment indicator **
0099T	Implantation of intrastromal corneal ring segments	R2*	R2*
0226T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed.	R2*	N1
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2*	R2*
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	R2*	R2*
10030	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity, abdominal wall, neck), percutaneous.	P2*	P2*
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed.	P3*	P3*
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy.	R2*	R2*

* If designation is temporary.

** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. According to the statutory formula, current law requires a negative update to the MPFS payment rates for CY 2015. For a discussion of those rates, we refer readers to the CY 2015 MPFS proposed rule.

We invite public comment on these proposals.

c. Proposed ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures.

(2) Proposed Changes To List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2015

As discussed in section II.A.2.e of this proposed rule, for CY 2015, we are proposing to create 28 comprehensive APCs to replace the current device dependent APCs and a few non-device dependent APCs under the OPPS; thus, there would be no device dependent APCs. We are proposing to define a comprehensive APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Because a comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, our OPPS proposal is to make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support the delivery of the primary service.

Unlike the OPPS claims processing system that can be configured to make a single payment for the encounter-based comprehensive service whenever a HCPCS code that is assigned to a comprehensive APC appears on the claim, the ASC claims-processing system does not allow for this type of conditional packaging. Therefore, we are proposing that all separately paid covered ancillary services that are provided integral to covered surgical procedures that would map to comprehensive APCs would continue to be separately paid under the ASC payment system instead of being packaged into the payment for the comprehensive APC as under the OPPS. The OPPS relative payment weights for the comprehensive APCs would include costs for ancillary services so we could duplicate payment if we based the ASC payment rate on the OPPS relative payment weights for the comprehensive APCs. Therefore, to avoid this issue, we are proposing that the ASC payment rates for these comprehensive APCs would be based on the CY 2015 OPPS relative payments weights that have been calculated using the standard APC ratesetting methodology for the primary service instead of the relative payment weights that are based on the comprehensive bundled service. For the same reason, under the ASC payment system, we also are proposing to use the standard OPPS APC ratesetting methodology instead of the comprehensive methodology to calculate the device offset percentage for comprehensive APCs for purposes of identifying device-intensive procedures and to calculate payment rates for device-intensive procedures assigned to comprehensive APCs.

Payment rates for ASC device-intensive procedures are based on a modified payment methodology to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures. Device-intensive procedures are currently defined as those procedures that are assigned to device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS. Because we are proposing to implement the comprehensive APC policy and, therefore, eliminate device-dependent APCs under the OPPS in CY 2015, we need to define ASC device-intensive procedures for CY 2015. We are proposing to define ASC device-intensive procedures as those procedures that are assigned to any APC (not only an APC formerly designated device-dependent) with a device offset percentage greater than 40 percent based on the standard OPPS APC ratesetting methodology. We believe that our proposal to lower the offset threshold from greater than 50 percent to greater than 40 percent better aligns with the OPPS device credit policy finalized for CY 2014 (78 FR 75006 and 75007) that applies to procedures with a significant device offset amount, which is defined as exceeding 40 percent of the APC cost. Because the ASC device-intensive methodology is applied to procedures with significant device costs, we believe that the definition of ''significant'' with regard to device-intensive procedures should match that used under the OPPS to determine ''significant'' device costs for the device credit policy. We are proposing changes to § 416.171(b)(2) to reflect this proposal.

We also are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with our proposed modified definition of device-intensive procedures, reflecting the proposed APC assignments of procedures and APC device offset percentages based on the CY 2013 OPPS claims and cost report data available for the proposed rule.

The ASC covered surgical procedures that we are proposing to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2015 are listed in Table 51 below. The CPT code, the CPT code short descriptor, the proposed CY 2015 ASC payment indicator (PI), the proposed CY 2015 OPPS APC assignment, the proposed CY 2015 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy would apply are also listed in Table 51 below. All of these procedures are included in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We invite public comment on these proposals.

d. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC policy with regard to payment for costly devices implanted in ASCs at no cost/full credit or partial credit as set forth in § 416.179 is consistent with the OPPS policy that was in effect until CY 2014. The established ASC policy reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68744).

As discussed in section IV.B. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPS, our policy was to reduce OPPS payment by 100 percent of the device offset amount

when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced device, capped at the device offset amount.

Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in that final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual amount received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

We are proposing to update the list of ASC covered device-intensive procedures, based on the revised device-intensive definition proposed above, that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2015. Table 51 below displays the ASC covered device-intensive procedures that we are proposing would be subject to the no cost/full credit or partial credit device adjustment policy for CY 2015. Specifically, when a procedure that is listed in Table 51 is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost to the ASC or with full credit. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure being furnished by the ASC.

For partial credit, we are proposing to reduce the payment for implantation procedures listed in Table 51 that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more of the cost of the new device. The ASC would append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in Table 51 that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more of the cost of a device. In order to report that they received a partial credit of 50 percent or more of the cost of a new device, ASCs would have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more of the cost of the replacement device. Beneficiary coinsurance would continue to be based on the reduced payment amount.

We currently apply the FB/FC policy to device-intensive procedures that involve devices that would be amenable to removal and replacement in a device recall or warranty situation. We are proposing to apply the FB/FC policy to all device-intensive procedures beginning in CY 2015 because, in addition to receiving devices at no cost/full credit or partial credit due to a device recall or warranty situation, ASCs also may receive devices at no cost/full credit or partial credit due to being part of an investigational device trial. In order to ensure that our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost/full credit or partial credit, we are proposing to apply our FB/FC policy to all device-intensive procedures.

TABLE 51—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2015, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH WE ARE PROPOSING THAT THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

HCPCS Code	Short descriptor	Proposed CY 2015 ASC PI	Proposed CY 2015 OPPS APC	Proposed CY 2015 device offset percent	Proposed FB/FC policy would apply
19298	Place breast rad tube/caths	J8	0648	0.4415	Yes.
19325	Enlarge breast with implant	J8	0648	0.4415	Yes.
19342	Delayed breast prosthesis	J8	0648	0.4415	Yes.
19357	Breast reconstruction	J8	0648	0.4415	Yes.
23515	Treat clavicle fracture	J8	0064	0.4308	Yes.
23585	Treat scapula fracture	J8	0064	0.4308	Yes.
23615	Treat humerus fracture	J8	0064	0.4308	Yes.
23616	Treat humerus fracture	J8	0064	0.4308	Yes.
23630	Treat humerus fracture	J8	0064	0.4308	Yes.
23670	Treat dislocation/fracture	J8	0064	0.4308	Yes.
24361	Reconstruct elbow joint	J8	0425	0.5661	Yes.
24363	Replace elbow joint	J8	0425	0.5661	Yes.
24365	Reconstruct head of radius	J8	0425	0.5661	Yes.
24366	Reconstruct head of radius	J8	0425	0.5661	Yes.
24370	Revise reconst elbow joint	J8	0425	0.5661	Yes.
24371	Revise reconst elbow joint	J8	0425	0.5661	Yes.
24435	Repair humerus with graft	J8	0425	0.5661	Yes.
24498	Reinforce humerus	J8	0425	0.5661	Yes.

TABLE 51—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2015, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH WE ARE PROPOSING THAT THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

HCPCS Code	Short descriptor	Proposed CY 2015 ASC PI	Proposed CY 2015 OPPS APC	Proposed CY 2015 device offset percent	Proposed FB/FC policy would apply
24515	Treat humerus fracture	J8	0064	0.4308	Yes.
24516	Treat humerus fracture	J8	0064	0.4308	Yes.
24545	Treat humerus fracture	J8	0064	0.4308	Yes.
24546	Treat humerus fracture	J8	0064	0.4308	Yes.
24575	Treat humerus fracture	J8	0064	0.4308	Yes.
24579	Treat humerus fracture	J8	0064	0.4308	Yes.
24586	Treat elbow fracture	J8	0064	0.4308	Yes.
24587	Treat elbow fracture	J8	0064	0.4308	Yes.
24615	Treat elbow dislocation	J8	0064	0.4308	Yes.
24635	Treat elbow fracture	J8	0064	0.4308	Yes.
24666	Treat radius fracture	J8	0064	0.4308	Yes.
25441	Reconstruct wrist joint	J8	0425	0.5661	Yes.
25442	Reconstruct wrist joint	J8	0425	0.5661	Yes.
25444	Reconstruct wrist joint	J8	0425	0.5661	Yes.
25446	Wrist replacement	J8	0425	0.5661	Yes.
25574	Treat fracture radius & ulna	J8	0064	0.4308	Yes.
25575	Treat fracture radius/ulna	J8	0064	0.4308	Yes.
25607	Treat fx rad extra-articul	J8	0064	0.4308	Yes.
25608	Treat fx rad intra-articul	J8	0064	0.4308	Yes.
25609	Treat fx radial 3+ frag	J8	0064	0.4308	Yes.
26686	Treat hand dislocation	J8	0064	0.4308	Yes.
27415	Osteochondral knee allograft	J8	0425	0.5661	Yes.
27428	Reconstruction knee	J8	0425	0.5661	Yes.
27438	Revise kneecap with implant	J8	0425	0.5661	Yes.
27440	Revision of knee joint	J8	0425	0.5661	Yes.
27442	Revision of knee joint	J8	0425	0.5661	Yes.
27443	Revision of knee joint	J8	0425	0.5661	Yes.
27446	Revision of knee joint	J8	0425	0.5661	Yes.
27745	Reinforce tibia	J8	0425	0.5661	Yes.
27759	Treatment of tibia fracture	J8	0064	0.4308	Yes.
27823	Treatment of ankle fracture	J8	0064	0.4308	Yes.
27827	Treat lower leg fracture	J8	0064	0.4308	Yes.
27828	Treat lower leg fracture	J8	0064	0.4308	Yes.
28415	Treat heel fracture	J8	0064	0.4308	Yes.
28715	Fusion of foot bones	J8	0425	0.5661	Yes.
33206	Insert heart pm atrial	J8	0089	0.6940	Yes.
33207	Insert heart pm ventricular	J8	0089	0.6940	Yes.
33208	Insrt heart pm atrial & vent	J8	0089	0.6940	Yes.
33210	Insert electrd/pm cath sngl	J8	0090	0.6828	Yes.
33211	Insert card electrodes dual	J8	0090	0.6828	Yes.
33212	Insert pulse gen sngl lead	J8	0090	0.6828	Yes.
33213	Insert pulse gen dual leads	J8	0089	0.6940	Yes.
33214	Upgrade of pacemaker system	J8	0089	0.6940	Yes.
33216	Insert 1 electrode pm-defib	J8	0090	0.6828	Yes.
33217	Insert 2 electrode pm-defib	J8	0090	0.6828	Yes.
33221	Insert pulse gen mult leads	J8	0655	0.7504	Yes.
33224	Insert pacing lead & connect	J8	0089	0.6940	Yes.
33227	Remove&replace pm gen singl	J8	0090	0.6828	Yes.
33228	Remv&replc pm gen dual lead	J8	0089	0.6940	Yes.
33229	Remv&replc pm gen mult leads	J8	0655	0.7504	Yes.
33230	Insrt pulse gen w/dual leads	J8	0107	0.7807	Yes.
33231	Insrt pulse gen w/mult leads	J8	0108	0.8095	Yes.
33233	Removal of pm generator	J8	0090	0.6828	Yes.
33240	Insrt pulse gen w/singl lead	J8	0107	0.7807	Yes.
33249	Nsert pace-defib w/lead	J8	0108	0.8095	Yes.
33262	Remv&replc cvd gen sing lead	J8	0107	0.7807	Yes.
33263	Remv&replc cvd gen dual lead	J8	0107	0.7807	Yes.
33264	Remv&replc cvd gen mult lead	J8	0108	0.8095	Yes.
33282	Implant pat-active ht record	J8	0090	0.6828	Yes.
37221	Iliac revasc w/stent	J8	0229	0.4981	Yes.
37225	Fem/popl revas w/ather	J8	0229	0.4981	Yes.
37226	Fem/popl revasc w/stent	J8	0229	0.4981	Yes.
37227	Fem/popl revasc stnt & ather	J8	0319	0.5796	Yes.
37228	Tib/per revasc w/tla	J8	0229	0.4981	Yes.
37229	Tib/per revasc w/ather	J8	0319	0.5796	Yes.
37230	Tib/per revasc w/stent	J8	0319	0.5796	Yes.
37231	Tib/per revasc stent & ather	J8	0319	0.5796	Yes.
37236	Open/perq place stent 1st	J8	0229	0.4981	Yes.

TABLE 51—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2015, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH WE ARE PROPOSING THAT THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

HCPCS Code	Short descriptor	Proposed CY 2015 ASC PI	Proposed CY 2015 OPPS APC	Proposed CY 2015 device offset percent	Proposed FB/FC policy would apply
37238	Open/perq place stent same	J8	0229	0.4981	Yes.
53440	Male sling procedure	J8	0385	0.5944	Yes.
53444	Insert tandem cuff	J8	0385	0.5944	Yes.
53445	Insert uro/ves nck sphincter	J8	0386	0.6919	Yes.
53447	Remove/replace ur sphincter	J8	0386	0.6919	Yes.
54400	Insert semi-rigid prosthesis	J8	0385	0.5944	Yes.
54401	Insert self-contd prosthesis	J8	0386	0.6919	Yes.
54405	Insert multi-comp penis pros	J8	0386	0.6919	Yes.
54410	Remove/replace penis prosth	J8	0386	0.6919	Yes.
54416	Remv/repl penis contain pros	J8	0386	0.6919	Yes.
55873	Cryoablate prostate	J8	0385	0.5944	Yes.
61885	Insrt/redo neurostim 1 array	J8	0039	0.8612	Yes.
61886	Implant neurostim arrays	J8	0318	0.8658	Yes.
61888	Revise/remove neuroreceiver	J8	0061	0.5642	Yes.
62361	Implant spine infusion pump	J8	0227	0.8060	Yes.
62362	Implant spine infusion pump	J8	0227	0.8060	Yes.
63650	Implant neuroelectrodes	J8	0061	0.5642	Yes.
63655	Implant neuroelectrodes	J8	0039	0.8612	Yes.
63663	Revise spine eltrd perq aray	J8	0061	0.5642	Yes.
63664	Revise spine eltrd plate	J8	0061	0.5642	Yes.
63685	Insrt/redo spine n generator	J8	0318	0.8658	Yes.
64553	Implant neuroelectrodes	J8	0061	0.5642	Yes.
64555	Implant neuroelectrodes	J8	0061	0.5642	Yes.
64561	Implant neuroelectrodes	J8	0061	0.5642	Yes.
64565	Implant neuroelectrodes	J8	0061	0.5642	Yes.
64568	Inc for vagus n elect impl	J8	0318	0.8658	Yes.
64569	Revise/repl vagus n eltrd	J8	0061	0.5642	Yes.
64575	Implant neuroelectrodes	J8	0061	0.5642	Yes.
64580	Implant neuroelectrodes	J8	0039	0.8612	Yes.
64581	Implant neuroelectrodes	J8	0061	0.5642	Yes.
64590	Insrt/redo pn/gastr stimul	J8	0039	0.8612	Yes.
65770	Revise cornea with implant	J8	0293	0.6588	Yes.
69714	Implant temple bone w/stimul	J8	0425	0.5661	Yes.
69715	Temple bne implnt w/stimulat	J8	0425	0.5661	Yes.
69718	Revise temple bone implant	J8	0425	0.5661	Yes.
69930	Implant cochlear device	J8	0259	0.8316	Yes.
0238T	Trluml perip athrc iliac art	J8	0319	0.5796	Yes.
0282T	Periph field stimul trial	J8	0061	0.5642	Yes.
0283T	Periph field stimul perm	J8	0318	0.8658	Yes.
0302T	Icar ischm mntrng sys compl	J8	0089	0.6940	Yes.
0303T	Icar ischm mntrng sys eltrd	J8	0090	0.6828	Yes.
0304T	Icar ischm mntrng sys device	J8	0090	0.6828	Yes.
0308T	Insj ocular telescope prosth	J8	0351	0.9004	Yes.
0316T	Replc vagus nerve pls gen	J8	0039	0.8612	Yes.
0319T	Insert subq defib w/eltrd	J8	0108	0.8095	Yes.
0320T	Insert subq defib electrode	J8	0090	0.6828	Yes.
0321T	Insert subq defib pls gen	J8	0107	0.7807	Yes.
0323T	Rmvl & replc subq pls gen	J8	0107	0.7807	Yes.
0334T	Perq stablj sacroiliac joint	J8	0425	0.5661	Yes.

We invite public comment on these proposals.

e. ASC Treatment of Surgical Procedures Proposed for Removal From the OPPS Inpatient Only List for CY 2015

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient only list for possible inclusion on the ASC list of covered surgical procedures. There are no procedures proposed for removal from the OPPS inpatient only list for CY 2015, so we are not proposing any procedures for possible inclusion on the ASC list of covered surgical procedures under this section.

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2015 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary services because of changes that are being proposed under the OPPS for CY 2015. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2014 may be proposed for packaged status under the CY 2015

OPPS and, therefore, also under the ASC payment system for CY 2015.

To maintain consistency with the OPPS, we are proposing that these services also would be packaged under the ASC payment system for CY 2015. Comment indicator ''CH,'' discussed in section XII.F. of this proposed rule, is used in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we are proposing a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2015.

Except for the Level II HCPCS codes and Level III CPT codes listed in Table 46 and Table 47 of this proposed rule, all ASC covered ancillary services and their proposed payment indicators for CY 2015 are included in Addendum BB to this proposed rule.

We invite public comment on this proposal.

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy for the revised ASC payment system, the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year is used to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2.'' Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and were, therefore, subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator ''A2'' because it is used to identify procedures that are exempted from application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75064 through 75090), we updated the CY 2013 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2,'' ''G2,'' and ''J8'' using CY 2012 data, consistent with the CY 2014 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2014 OPPS device offset percentages.

Payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2015 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2014 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2014 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2014 payment rate for the procedure according to the final policy of the revised ASC payment system (§ 416.171(d)).

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2015

We are proposing to update ASC payment rates for CY 2015 using the established rate calculation methodologies under § 416.171 and using our proposed modified definition of device-intensive procedures, as discussed above. Because the proposed OPPS relative payment weights are based on geometric mean costs for CY 2015, the ASC system will use geometric means to determine proposed relative payment weights under the ASC standard methodology. We are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2.''

We are proposing that payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') and device-intensive procedures (payment indicator ''J8'') be calculated according to our established policies and, for device-intensive procedures, using our proposed modified definition of device-intensive procedures, as discussed above. Thus, we are proposing to update the payment amount for the service portion of the device-intensive procedures using the ASC standard ratesetting methodology and the payment amount for the device portion based on the proposed CY 2015 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures is at the lesser of the proposed CY 2015 MPFS nonfacility PE RVU-based amount or the proposed CY 2015 ASC payment amount calculated according to the ASC standard ratesetting methodology.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package device removal codes under the OPPS. Under the OPPS, a conditionally packaged code (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Thus, no Medicare payment would be made when a device removal procedures is performed in an ASC without another surgical procedure included on the claim so no Medicare payment would be made if a device was removed but not replaced. To address this concern, for the 71 device removal procedures that are conditionally packaged in the OPPS (status indicator ''Q2''), we assigned the current ASC payment indicators associated with these procedures and continued to provide separate payment in CY 2014. For CY 2015, we are proposing to continue this policy for the 71 device removal procedures for these same reasons.

We invite public comment on these proposals.

c. Waiver of Coinsurance and Deductible for Certain Preventive Services

Section 1833(a)(1) and section 1833(b)(1) of the Act waive the coinsurance and the Part B deductible for those preventive services under section 1861(ddd)(3)(A) of the Act as described in section 1861(ww)(2) of the Act (excluding electrocardiograms) that are recommended by the United States

Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. Section 1833(b) of the Act also waives the Part B deductible for colorectal cancer screening tests that become diagnostic. In the CY 2011 OPPS/ASC final rule with comment period, we finalized our policies with respect to these provisions and identified categories of services and the ASC covered surgical procedures and covered ancillary services that are preventive services that are recommended by the USPSTF with a grade of A or B for which the coinsurance and the deductible are waived. For a complete discussion of our policies and categories of services, we refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72047 through 72049). We are not proposing any changes to our policies or the categories of services for CY 2015. We identify the specific services with a double asterisk in Addenda AA and BB to this proposed rule.

d. Proposed Payment for Cardiac Resynchronization Therapy Services

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD). CRT performed by the implantation of an ICD along with a pacing electrode is referred to as ''CRT–D.'' In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2012 ASC payment rate for CRT–D services based on the OPPS payment rate applicable to APC 0108 when procedures described by CPT codes 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system) (list separately in addition to code for primary procedure)) and 33249 (Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber) are performed on the same date of service in an ASC. ASCs use the corresponding HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service. When not performed on the same day as the service described by CPT code 33225, ASC payment for the service described by CPT code 33249 is based on APC 0108 using the device-intensive methodology. When not performed on the same day as the service described by CPT code 33249, ASC payment for the service described by CPT code 33225 is based on APC 0655 using the device-intensive methodology. For a complete discussion of our policy regarding payment for CRT–D services in ASCs, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74427 through 74428).

For CY 2015, we are proposing that CPT code 33249, the primary code for CRT–D services, continue to be assigned to APC 0108, and that payment for CPT code 33225 be packaged under the OPPS. Consequently, we also are proposing that CPT code 33249 would continue to be assigned to APC 0108 and payment for CPT code 33225 would be packaged into the payment for the primary covered surgical procedure (for example, CPT code 33249) under the ASC payment system for CY 2015. Because we are proposing to package CPT code 33225 packaged under the ASC payment system and, therefore, it would not receive separate payment, it would no longer be necessary that ASCs use the HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service.

We invite public comment on these proposals.

e. Payment for Low Dose Rate (LDR) Prostate Brachytherapy Composite

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy); and CPT code 77778 (Interstitial radiation source application; complex). Generally, the component services represented by both codes are provided in the same operative session on the same date of service to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2013 ASC payment rate for LDR prostate brachytherapy services based on the OPPS relative payment weight applicable to APC 8001 when CPT codes 55875 and 77778 are performed on the same date of service in an ASC. ASCs use the corresponding HCPCS Level II G-code (G0458) for proper reporting when the procedures described by CPT codes 55875 and 77778 are performed on the same date of service, and therefore receive the appropriate LDR prostate brachytherapy composite payment. When not performed on the same day as the service described by CPT code 55875, the service described by CPT code 77778 will be assigned to APC 0651. When not performed on the same day as the service described by CPT code 77778, the service described by CPT code 55875 will be assigned to APC 0162. For a complete discussion of our policy regarding payment for LDR prostate brachytherapy services in ASCs, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68457). We are not proposing any changes to our current policy regarding ASC payment for LDR prostate brachytherapy services for CY 2015.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our final payment policies under the revised ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N,'' ''Q1,'' and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169; 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indictor ''N1'') under the ASC payment system.

Thus, our final policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates. We generally pay for separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount, regardless of which is lower. This modification to the ASC payment methodology for ancillary services was finalized in response to a comment on the CY 2011 OPPS/ASC proposed rule that suggested it is inappropriate to use the MPFS-based payment methodology for nuclear medicine procedures because the associated diagnostic radiopharmaceutical, although packaged under the ASC payment system, is separately paid under the MPFS (42 CFR 416.171(d)(1)). We set the payment indicator to ''Z2'' for these nuclear medicine procedures in the ASC setting so that payment for these procedures would be based on the OPPS relative payment weight rather than the MPFS nonfacility PE RVU-based amount to ensure that the ASC will be compensated for the cost associated with the diagnostic radiopharmaceuticals.

In addition, because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the MPFS), we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430) to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight and will, therefore, include the cost for the contrast agent (42 CFR 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through status under the OPPS. These categories do not have prospectively established ASC payment rates according to the final policies for the revised ASC payment system (72 FR 42502 and 42508 through 42509; 42 CFR 416.164(b)). Under the revised ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Currently, the one device that is eligible for pass-through payment in the OPPS is described by HCPCS code C1841 (Retinal prosthesis, includes all internal and external components). The payment amount for HCPCS code C1841 under the ASC payment system is contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. (We note that the cost for the new pass-through device would not be included in the APC weight since historical claims are used to establish the OPPS relative weights). We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through status. There are no other device costs included in the APC for the surgical procedure associated with HCPCS code C1841. Therefore, payment for the associated surgical procedure is made according to the standard methodology and no device offset is applied. HCPCS code C1841 was approved for pass-through payment effective October 1, 2013, and will continue to be eligible for pass-through payment in CY 2015.

b. Proposed Payment for Covered Ancillary Services for CY 2015

For CY 2015, we are proposing to update the ASC payment rates and to make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2015 OPPS and ASC payment rates. We also are proposing to continue to set the CY 2015 ASC payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the proposed OPPS payment rates for CY 2015.

Consistent with established ASC payment policy (72 FR 42497), we are proposing that the proposed CY 2015 payment for separately payable covered radiology services be based on a comparison of the proposed CY 2015 MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2015 MPFS proposed rule) and the proposed CY 2015 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts (except as discussed below for nuclear medicine procedures and radiology services that use contrast agents). We are proposing that payment for a radiology service would be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged or conditionally packaged under the OPPS. The payment indicators in Addendum BB to this proposed rule indicate whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU-based amount or the ASC standard ratesetting methodology, or whether payment for a radiology service is packaged into the payment for the covered surgical procedure (payment indicator ''N1''). Radiology services that we are proposing to pay based on the ASC standard ratesetting methodology are assigned payment indicator ''Z2'' (proposed revised definition, as discussed below: Radiology *or diagnostic* service paid

separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight), and those for which the proposed payment is based on the MPFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3'' (proposed revised definition, as discussed below: Radiology *or diagnostic* service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs).

As finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment for these procedures will be based on the OPPS relative payment weight (rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower) and, therefore, will include the cost for the diagnostic radiopharmaceutical. We are proposing to continue this modification to the payment methodology in CY 2015 and, therefore, set the payment indicator to ''Z2'' for nuclear medicine procedures.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), payment indicators for radiology services that use contrast agents are set to ''Z2'' so that payment for these procedures will be based on the OPPS relative payment weight and, therefore, will include the cost for the contrast agent. We are proposing to continue this modification to the payment methodology in CY 2015 and, therefore, are proposing to assign the payment indicator ''Z2'' to radiology services that use contrast agents.

Covered ancillary services are items and services that are integral to a covered surgical procedure performed in an ASC for which separate payment may be made under the ASC payment system (see 42 CFR 416.2). Covered ancillary services include, among other categories of items and services, certain radiology services, including diagnostic imaging services, for which separate payment is allowed under the OPPS when these services are necessary for the successful completion of a surgical procedure and are performed in the ASC immediately preceding, during, or immediately following the covered surgical procedure, as evidenced by the service being provided on the same day as a covered surgical procedure (see 42 CFR 416.164(b)(5)). Currently, there are certain non-imaging diagnostic tests for which payment is not made under Medicare Part B when provided in an ASC setting although these tests are paid under the OPPS. Therefore, we believe that certain non-imaging diagnostic tests for which separate payment is allowed under the OPPS should be considered covered ancillary services and separately paid when these tests are required for the successful performance of the surgery and are performed in the ASC on the same day as a covered surgical procedure.

Therefore, we are proposing that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS be covered ancillary services when they are integral to an ASC covered surgical procedure. We believe that adopting such a payment policy is reasonable and appropriate to ensure access to these tests in ASCs and is consistent with the OPPS. We are proposing that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT.

We are proposing to pay for these tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology, because this would ensure appropriate and equitable payment for these diagnostic tests provided integral to covered surgical procedures and not provide a payment incentive for migration of the tests from physician offices to ASCs. Further, we believe these diagnostic tests are similar to the covered ancillary services that are radiology services and this is the payment methodology we use for those services. We are proposing that the diagnostic tests for which the proposed payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' (proposed revised definition: Radiology *or diagnostic* service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight), and those for which the proposed payment is based on the MPFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3'' (proposed revised definition: Radiology *or diagnostic* service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs). We are proposing changes to the definitions for payment indicators ''Z2'' and ''Z3,'' as detailed in section XII.F.2 of this preamble below, and are proposing changes to §§ 416.164(a)(11) and (b)(5) as well as § 416.171(b)(1) to reflect these proposals.

We have identified one diagnostic test that is within the medicine range of CPT codes and for which separate payment is allowed under the OPPS: CPT code 91035 (Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation). We are proposing to add this code to the list of ASC covered ancillary services and are proposing separate ASC payment as a covered ancillary service for this code beginning in CY 2015 when the test is integral to an ASC covered surgical procedure. We would expect the procedure described by CPT code 91035 to be integral to the endoscopic attachment of the electrode to the esophageal mucosa.

Most covered ancillary services and their proposed payment indicators are listed in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site).

We invite public comment on these proposals.

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of new technology intraocular lenses (NTIOLs) is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information that is found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an existing NTIOL Class'' posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html.*
- We announce annually in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Pub. L. 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following

publication of the list of requests in the proposed rule.

- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

○ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments;

○ When a new NTIOL class is created, we identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

○ The date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class would be set prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

○ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2015

We did not receive any requests for review to establish a new NTIOL class for CY 2015 by March 3, 2014, the due date published in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75085).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2015.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we also created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC list of covered services prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' is also assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In the CY 2015 OPPS/ASC final rule with comment period, we will respond to public comments and finalize the ASC treatment of all codes that are labeled with comment indicator ''NI'' in Addenda AA and BB to the CY 2014 OPPS/ASC final rule with comment period.

The ''CH'' comment indicator is used in Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and next calendar year; an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

2. Proposed ASC Payment and Comment Indicators

We are not proposing any changes to the definitions of the ASC comment indicators for CY 2015. In order to incorporate changes associated with our proposal for CY 2015, as detailed above in section XII.D.2.b. of this proposed rule, that certain diagnostic tests qualify as covered ancillary services when provided integral to an ASC covered surgical procedure, we are proposing to revise the definitions for payment indicators ''Z2'' and ''Z3'' to add the words ''or diagnostic'' after ''Radiology'' so that the proposed definition for payment indicator ''Z2'' would be ''Radiology *or diagnostic* service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight,'' and the proposed definition for payment indicator ''Z3'' would be ''Radiology *or diagnostic* service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs.'' We refer readers to Addenda DD1 and DD2 to this proposed rule (which are available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2015 update.

G. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007 as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget

neutral in subsequent calendar years (72 FR 42532 through 42533; 42 CFR 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures and covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2.b. of this proposed rule), the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor cost when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003. In other words, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available raw pre-floor and pre-reclassified hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. In addition, use of the unadjusted hospital wage data avoids further reductions in certain rural statewide wage index values that result from reclassification. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs.

On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*.) The pre-floor and pre-reclassified hospital wage indexes for FY 2014 do not reflect OMB's new area delineations and, because the ASC wage indexes are the pre-floor and pre-reclassified hospital wage indexes, the CY 2014 ASC wage indexes do not reflect the OMB changes. As discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28054 through 28068), we are proposing to use the new CBSAs delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index. Therefore, because the ASC wage indexes are the pre-floor and pre-reclassified hospital wage indexes, the proposed CY 2015 ASC wage indexes reflect the new OMB delineations. As discussed in section XII.G.2.b. of this proposed rule, we are proposing a transition to these new OMB delineations in certain situations for CY 2015.

We note that in certain instances there might be urban or rural areas for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). For example, for CY 2014, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA) and CBSA 08 (Rural Delaware).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). In other situations, where there are no IPPS hospitals located in a relevant labor market area, we will continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

2. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2015 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). Consistent with our established policy, we are proposing to scale the CY 2015 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2013, we are proposing to compare the total payment using the CY 2014 ASC relative payment weights with the total payment using the CY 2015 relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2014 and CY 2015. We are

proposing to use the ratio of CY 2014 to CY 2015 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2015. The proposed CY 2015 ASC scaler is 0.9142 and scaling would apply to the ASC relative payment weights of the covered surgical procedures and covered ancillary radiology services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of this proposed rule, we have available 98 percent of CY 2013 ASC claims data.

To create an analytic file to support calculation of the weight scaler and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2013 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2013 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for this proposed rule, is posted on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html*.

b. Proposed Transition Period to New OMB Delineations for ASC Wage Index

As discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28054 through 28055), we are proposing to use the new CBSA delineations issued by OMB in OMB Bulletin 13–01 dated February 28, 2013 for the IPPS hospital wage index. Therefore, because the ASC wage indexes are the pre-floor and pre-reclassified hospital wage indexes, the proposed CY 2015 ASC wage indexes reflect the new OMB delineations. While we believe that instituting the latest OMB labor market area delineations would create a more accurate and up-to-date wage index system, we also recognize that implementing the new OMB delineations may cause some short-term instability in ASC payments; therefore, we are proposing a transition to the new OMB delineations similar to what has been proposed for the IPPS for FY 2015 (79 FR 28062) and the OPPS as described in section II.C of this proposed rule. Specifically for ASCs, we are proposing a 1-year blended wage index for all ASCs that would experience any decrease in their actual wage index exclusively due to the implementation of the new OMB delineations. For ASCs where the CY 2015 ASC wage index with the CY 2015 CBSAs would be lower than with the CY 2014 CBSAs, we are proposing that the CY 2015 ASC wage index would be 50 percent of the ASC wage index based on the CY 2014 CBSA and 50 percent of the ASC wage index based on the new CY 2015 CBSA. We believe a 1-year 50/50 blended wage index would mitigate the short-term instability and negative payment impacts due to the proposed implementation of the new OMB delineations, providing ASCs that would be negatively impacted by the new OMB delineations with a transition period during which they may adjust to their new geographic CBSA. We believe that a longer transition period would reduce the accuracy of the overall labor market area wage index system.

c. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2015 ASC payment system, we are proposing to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2015, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2013 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2015 ASC wage indexes. Specifically, holding CY 2013 ASC utilization and service-mix and the proposed CY 2015 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2014 ASC wage indexes and the total adjusted payment using the proposed CY 2015 ASC wage indexes (which reflect the new OMB delineations and would include any applicable transition period). We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2014 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2015 ASC wage indexes and applied the resulting ratio of 0.9983 (the proposed CY 2015 ASC wage index budget neutrality adjustment) to the CY 2014 ASC conversion factor to calculate the proposed CY 2015 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, ''if the Secretary has not updated amounts established'' under the revised ASC payment system in a calendar year, the payment amounts ''shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.'' The statute, therefore, does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI–U (referred to as the CPI–U update factor).

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that ''any annual update under [the ASC payment] system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)'' of the Act effective with the calendar year beginning January 1, 2011. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending

with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). Clause (iv) of section 1833(i)(2)(D) of the Act authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) of section 1833(i)(2)(D) of the Act states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASCQR Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), we finalized a methodology to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for the CY 2014 payment determination and subsequent years. The application of the 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We amended §§ 416.160(a)(1) and 416.171 to reflect these policies.

In accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the ''percentage increase'' in the CPI–U, which we interpret cannot be a negative percentage. Thus, in the instance where the percentage change in the CPI–U for a year is negative, we would hold the CPI–U update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the rules established by the Secretary in accordance with section 1833(i)(7) of the Act. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction, by the MFP adjustment, and states that application of the MFP adjustment to the annual update factor after application of any quality reporting reduction may result in the update being less than zero for a year. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064) for illustrative examples of how the MFP adjustment is applied to the ASC payment system.

For this proposed rule, based on IHS Global Insight's (IGI's) 2014 first quarter forecast with historical data through 2013 fourth quarter, for the 12-month period ending with the midpoint of CY 2015, the CPI–U update is projected to be 1.7 percent. Also, based on IGI's 2014 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2015 is projected to be 0.5 percent. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of CMS' market baskets as well as the CPI–U and MFP. We finalized the methodology for calculating the MFP adjustment in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) as revised in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301). The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the CPI–U for ASCs that fail to meet the ASCQR Program requirements.

We are proposing to reduce the CPI–U update of 1.7 percent by the MFP adjustment of 0.5 percentage point, resulting in an MFP-adjusted CPI–U update factor of 1.2 percent for ASCs meeting the quality reporting requirements. Therefore, we are proposing to apply a 1.2 percent MFP-adjusted CPI–U update factor to the CY 2014 ASC conversion factor for ASCs meeting the quality reporting requirements. We are proposing to reduce the CPI–U update of 1.7 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then apply the 0.5 percentage point MFP reduction. Therefore, we are proposing to apply a −0.8 percent quality reporting/MFP-adjusted CPI–U update factor to the CY 2014 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also are proposing that if more recent data are subsequently available (for example, a more recent estimate of the CY 2015 CPI–U update and MFP adjustment), we would use such data, if appropriate, to determine the CY 2015 ASC update for the final rule with comment period.

For CY 2015, we also are proposing to adjust the CY 2014 ASC conversion factor ($43.471) by the proposed wage index budget neutrality factor of 0.9983 in addition to the MFP-adjusted update factor of 1.2 percent discussed above, which results in a proposed CY 2015 ASC conversion factor of $43.918 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are proposing to adjust the CY 2014 ASC conversion factor ($43.471) by the proposed wage index budget neutrality factor of 0.9983 in addition to the quality reporting/MFP-adjusted update factor of −0.8 percent discussed above, which results in a proposed CY 2015 ASC conversion factor of $43.050.

We invite public comment on these proposals.

3. Display of Proposed CY 2015 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) display the proposed updated ASC payment rates for CY 2015 for covered surgical procedures and covered ancillary services, respectively. The payment rates included in these addenda reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the proposed CY 2015 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''Proposed to be Subject to Multiple Procedure Discounting'' indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session. Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator

for CY 2015. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that the payment indicator assignment is an interim assignment that is open to comment in the final rule with comment period.

The values displayed in the column titled ''Proposed CY 2015 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2015. The proposed payment weights for all covered surgical procedures and covered ancillary services whose ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the proposed CY 2015 payment rate displayed in the ''Proposed CY 2015 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2015 Payment Weight'' column was multiplied by the proposed CY 2015 conversion factor of $43.918. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as discussed in section XII.H.2.b. of this proposed rule).

In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2015 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2015 Payment'' column displays the proposed CY 2015 national unadjusted ASC payment rates for all items and services. The proposed CY 2015 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in April 2014.

Addendum E provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for FY 2015.

III. Hospital Outpatient Quality Reporting Program Updates

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient health care for Medicare beneficiaries. In pursuit of these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The Hospital OQR Program has generally been modeled after the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program).

In addition to the Hospital IQR and Hospital OQR Programs, CMS has implemented quality reporting programs for other care settings that provide financial incentives for the reporting of quality data to CMS. These additional programs include reporting for care furnished by:

- Physicians and other eligible professionals, under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI));
- Inpatient rehabilitation facilities, under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals, under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program;
- PPS-exempt cancer hospitals, under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers, under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities, under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program;
- Home health agencies, under the Home Health Quality Reporting Program (HH QRP); and
- Hospices, under the Hospice Quality Reporting Program.

In addition, CMS has implemented two value-based purchasing programs, the Hospital Value-Based Purchasing (Hospital VBP) Program and the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP), that link payment to performance.

In implementing the Hospital OQR Program and other quality reporting programs, we have focused on measures that have high impact and support national priorities for improved quality and efficiency of care for Medicare beneficiaries as reflected in the National Quality Strategy (NQS) and CMS Quality Strategy, as well as conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. To the extent possible under various authorizing statutes, our ultimate goal is to align the clinical quality measure requirements of our various quality reporting programs. As appropriate, we will consider the adoption of measures with electronic specifications to enable the collection of this information as part of care delivery.

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68467 through 68469) for a discussion on the principles underlying consideration for future measures that we intend to use in implementing this and other quality reporting programs.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Measure Updates and Data Publication

a. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we continue to develop the Hospital OQR Program. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244*.

Many of the quality measures used in Medicare and Medicaid reporting programs are endorsed by the National Quality Forum (NQF). We note that not all of the measures adopted by the Hospital OQR Program are NQF-endorsed, nor is NQF endorsement a program requirement (section 1833(t)(17)(C)(i) of the Act). As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards (owners/developers) to submit annual measure maintenance updates and undergo maintenance of endorsement

review every 3 years. In the measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes with the NQF on an annual basis. The NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific 3-year cycle.

We note that the NQF's annual or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to measures in order to maintain endorsement status. Other non-NQF measures may undergo maintenance changes as well. We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates into the measure specifications for measures that we have adopted for the Hospital OQR Program so that these measure specifications remain current. We also recognize that some changes to measures are substantive in nature and might not be appropriate for adoption using a subregulatory process.

Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68469 through 68470) we finalized our proposal to follow the same process for updating Hospital OQR Program measures that we adopted for the Hospital IQR Program measures, including the subregulatory process for making updates to the adopted measures (77 FR 53504 through 53505). This process expanded upon the subregulatory process for updating measures that we finalized in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767).

b. Public Display of Quality Measures

We refer readers to the CY 2014 OPPS/ASC proposed rule (78 FR 43645) for a discussion of our policy for the publication of Hospital OQR Program data on the *Hospital Compare* Web site and noninteractive CMS Web sites.

We are not proposing any changes to our policies on the public display of quality measures.

B. Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471), we finalized a policy that once a quality measure is adopted for the Hospital OQR Program, it is retained for use in subsequent years unless otherwise specified.

We are not proposing any changes to the process for retaining measures previously adopted.

C. Removal of Quality Measures From the Hospital OQR Program Measure Set

1. Considerations in Removing Quality Measures From the Hospital OQR Program

In the FY 2010 IPPS/LTCH PPS final rule, we finalized a process for immediate retirement, which we later termed ''removal'' (74 FR 43863), of Hospital IQR Program measures based on evidence that the continued use of the measure as specified raised patient safety concerns. We adopted the same immediate measure retirement policy for the Hospital OQR Program in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635). We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term ''retirement'' to ''removal'' in the Hospital OQR Program.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), we finalized a set of criteria for determining whether to remove measures from the Hospital IQR Program. These criteria are: (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); (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection or public reporting of a measure leads to negative unintended consequences such as patient harm. These criteria were suggested through public comment on proposals for the Hospital IQR Program, and we determined that these criteria are also applicable in evaluating the Hospital OQR Program quality measures for removal.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473), we finalized our proposal to apply these measure removal criteria in the Hospital OQR Program as well. In addition to the Hospital IQR Program's criteria, we consider eliminating measure redundancy and incorporating the views of the Measures Application Partnership (MAP) when evaluating measures for removal.

2. Proposed Criteria for Removal of ''Topped-Out'' Measures

In this proposed rule, we are proposing to refine the criteria for determining when a measure is ''topped-out.'' We had previously finalized that a measure is ''topped-out'' when measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures) (77 FR 68472). We do not believe that measuring hospital performance on ''topped-out'' measures provides meaningful information on the quality of care provided by hospitals. We further believe that quality measures, once ''topped-out,'' represent care standards that have been widely adopted by hospitals. We believe such measures should be considered for removal from the Hospital OQR Program because their associated reporting burden may outweigh the value of the quality information they provide.

In order to determine ''topped-out'' status, we are proposing to apply the following two criteria, the first of which was previously adopted by the Hospital VBP Program in the Hospital Inpatient VBP Program final rule (76 FR 26496 through 26497). The second criterion is a modified version of what was previously adopted by the Hospital VBP Program in the above mentioned final rule, with the change from the ''less than'' operator (<) to the ''less than or equal to'' operator (≤). Specifically, we are proposing that a measure under the Hospital OQR Program is ''topped-out'' when it meets both of the following criteria:

- Statistically indistinguishable performance at the 75th and 90th percentiles; and
- A truncated coefficient of variation less than or equal to 0.10.

To identify if a measure has statistically indistinguishable performance at the 75th and 90th percentiles, we would determine whether the difference between the 75th and 90th percentiles for a measure is within two times the standard error of the full dataset. The coefficient of variation (CV) is a descriptive statistic that expresses the standard deviation as a percentage of the sample mean; this provides a statistic that is independent of the units of observation. Applied to this analysis, a large CV would indicate a broad distribution of individual hospital scores, with large and

presumably meaningful differences between hospitals in relative performance. A small CV would indicate that the distribution of individual hospital scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions among individual hospitals' measure performance. The truncated CV excludes observations whose rates are below the 5th percentile and above the 95th percentile. We have proposed these same criteria for when we would consider a measure to be ''topped-out'' for the Hospital VBP Program (79 FR 28119) and the Hospital IQR Program (79 FR 28219), and we are also proposing them for the ASCQR Program in section XIV.B.3. of this proposed rule.

We invite public comment on this proposal.

3. Proposed Removal of Measures From the Hospital OQR Program for the CY 2017 Payment Determination and Subsequent Years

We are proposing to remove three measures for the CY 2017 payment determination and subsequent years: OP–4, OP–6, and OP–7. Based on our analysis of Hospital OQR Program chart-abstracted measure data for January 1, 2013–June 30, 2013 (Q1–Q2) encounters, the following measures meet both: (1) The previously finalized criteria for being ''topped-out,'' that is, measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (77 FR 68472), and (2) the two criteria we are proposing in section XIII.C.2. of this proposed rule for determining ''topped-out'' status. These measures are:

- OP–4: Aspirin at Arrival (NQF #0286);
- OP–6: Timing of Antibiotic Prophylaxis; and
- OP–7: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528).

Therefore, we are proposing to remove these three measures from the Hospital OQR Program beginning with the CY 2017 payment determination.

We believe that removal is appropriate as there is little room for improvement for these measures, all of which address standard clinical care. In addition, by removing these measures, we would alleviate the maintenance costs and administrative burden to hospitals associated with retaining them. Should we determine that hospital adherence to these practices has unacceptably declined, we would repropose these measures in future rulemaking. In addition, we would comply with any requirements imposed by the Paperwork Reduction Act before reinstituting these measures. We have also proposed to remove three measures under the Hospital IQR Program that are similar to these measures. We note that the similar measures are called AMI–1, SCIP-Inf-1, and SCIP-Inf-2, respectively, in the Hospital IQR Program and that we proposed to retain SCIP-Inf-1 and SCIP-Inf-2 as voluntarily reported electronic clinical quality measures (79 FR 28219 through 28220 and 79 FR 29242).

We invite public comment on these proposals.

HOSPITAL OQR PROGRAM MEASURES PROPOSED FOR REMOVAL FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure
0286	OP–4: Aspirin at Arrival.
N/A	OP–6: Timing of Prophylactic Antibiotics.
0528	OP–7: Prophylactic Antibiotic Selection for Surgical Patients.

D. Quality Measures Previously Adopted for the CY 2016 Payment Determination and Subsequent Years

As previously discussed, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471), we finalized a policy that, beginning CY 2013, when we adopt measures for the Hospital OQR Program, these measures are automatically adopted for all subsequent years' payment determinations, unless we propose to remove, suspend, or replace the measures. The table below lists 27 measures that we adopted for the CY 2016 payment determination and subsequent years under the Hospital OQR Program.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
N/A	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival****.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival**.
0289	OP–5: Median Time to ECG.
N/A	OP–6: Timing of Prophylactic Antibiotics**.
0528	OP–7: Prophylactic Antibiotic Selection for Surgical Patients**.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.
N/A	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF No.	Measure name
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP–22: ED—Left Without Being Seen****.
0661	OP–23: ED—Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures*.
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients.
0659	OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery***.

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889963089&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D1r_OP26MIF_v+6+0b.pdf&blobcol=urldata&blobtable=MungoBlobs*.

** Measures we are proposing for removal beginning with the CY 2017 payment determination in section XIII.C.3. of this proposed rule.

*** Measure we are proposing for voluntary data collection in section XIII.D.3.b. of this proposed rule.

**** Name has been updated to correspond with NQF-endorsed name.

1. Data Submission Requirements for OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) Reported via NHSN for the CY 2017 Payment Determination and Subsequent Years

The Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF #0431) was finalized for the Hospital OQR Program in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100). We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75116 through 75117) for a discussion of the previously finalized data submission requirements for this measure. This measure was previously finalized for the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51636). In this proposed rule, we are making two clarifications: (1) Correcting the previously stated submission deadline; and (2) clarifying that hospitals should report the Influenza Vaccination Coverage among HCP (NQF #0431) measure by CMS Certification Number (CCN) rather than separately reporting for both the inpatient and outpatient setting.

a. Clarification of Submission Deadline and Data Submitted

We note that there was a typographical error in our discussion in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75116 through 75117); and we are proposing to remedy that error through this proposed rule. Specifically, we finalized that the first deadline for hospitals to submit NHSN HAI measure data would be ''May 15, 2015 with respect to the October 1, 2015 through March 31, 2015 encounter period'' (78 FR 75117). We are clarifying here that the beginning of the encounter period should be ''October 1, 2014'' instead of ''October 1, 2015.'' In addition, we are clarifying here that the data to be submitted are more specifically referred to as ''health care personnel influenza vaccination summary reporting data'' instead of ''HAI measure data.''

b. Clarification on Reporting by CMS Certification Number (CCN)

We received public comment about the burden of separately collecting HCP influenza vaccination status for both the hospital inpatient and outpatient settings. We believe that reporting a single vaccination count for each health care facility enrolled in NHSN will be less burdensome to facilities. Therefore, in response to these concerns, we collaborated with CDC to clarify in an Operational Guidance document, that beginning with the 2014–2015 influenza season (CY 2014 reporting period and CY 2016 payment determination), facilities should collect and report a single vaccination count for each health care facility by CNN, instead of separately reporting by inpatient or outpatient setting. We are clarifying here that facilities will report data to NHSN by enrolled facility. CDC will then submit the data on behalf of the facilities by CNN. The CDC also has produced an Operational Guidance document regarding reporting for this measure, which can be found at: *http://www.cdc.gov/nhsn/PDFs/HCP/Operational-Guidance-ACH-HCP-Flu.pdf*.

Reporting data in this way will allow health care facilities with multiple care settings to simplify data collection and submit a single count applicable across the inpatient and outpatient settings. We will then publicly report the percentage of HCP who received an influenza vaccination per CCN. This single count per CCN will inform the public of the percentage of vaccinated HCP at a particular healthcare facility, which would still provide meaningful data and help to improve the quality of care. Specific details on data submission for this measure can be found at: *http://www.cdc.gov/nhsn/acute-care-hospital/hcp-vaccination/* and at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html*.

This clarification regarding the reporting of a single count applicable across the inpatient and outpatient settings was also noted in the FY 2015 IPPS/LTCH PPS proposed rule for the Hospital IQR Program (79 FR 28221). We note that, in that rule, we refer to reporting specifically by CNN rather than by ''enrolled facility''.

2. Delayed Data Collection for OP–29 and OP–30

In the CY 2014 OPPS/ASC final rule with comment period, we adopted OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0558) (78 FR 75102) and OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) (78 FR 75102), both chart-abstracted measures, and proposed that aggregate data would be collected via an online Web-based tool (the QualityNet Web site) beginning with the CY 2016 payment determination. We finalized that, for the CY 2016 payment determination, hospitals would be required to submit aggregate-level encounter data between July 1, 2015 and November 1, 2015 for data collected

during January 1, 2014–December 31, 2014 (78 FR 75114 through 75115).

On December 31, 2013, we issued guidance stating that we would delay the implementation of OP–29 and OP–30 for 3 months for the CY 2016 payment determination, changing the encounter period from January 1, 2014–December 31, 2014 to April 1, 2014–December 31, 2014 (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228721506778*). The data submission window for data collected from April 1, 2014–December 31, 2014 is still July 1, 2015–November 1, 2015. The data submission windows and the encounter periods for subsequent years remains as previously finalized (78 FR 75114); hospitals are to submit Web-based data between July 1 and November 1 of the year prior to a payment determination with respect to the encounter period of January 1 to December 31 of 2 years prior to a payment determination year.

3. OP–31: Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery

In the CY 2014 OPPS/ASC final rule with comment period, we adopted OP–31 Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) for the CY 2016 payment determination and subsequent years (78 FR 75103). This measure assesses the rate of patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery based on completing both a pre-operative and post-operative visual function survey.

In this proposed rule, we are: (1) Correcting our response to public comments, (2) noting our decision to delay data collection for the CY 2016 payment determination, and, (3) proposing voluntary data collection for the CY 2017 payment determination and subsequent years for OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

a. Correction of Response to Public Comments

In the CY 2014 OPPS/ASC final rule with comment period, we stated in response to commenters concerned that the proposed chart-abstracted measures had not been field-tested, that, ''all three measures that we are finalizing . . . were field-tested in the HOPD facility setting by the measure stewards. These three measures are: (1) Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); (2) Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); and (3) [OP–31] Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)'' (78 FR 75099 through 75100).

We inadvertently misstated that the OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) had been field-tested in the HOPD setting, and we are clarifying here that this measure has not been field-tested in that setting. We note that in considering and selecting this measure, however, we took into account other principles or factors, including: NQS goals, type of measure, HHS Strategic Plan and Initiatives, NQF endorsement, MAP support, stakeholder input, alignment with quality goals and settings, relevance, utility and burden. More information about these principles can be found in the CY 2014 OPPS/ASC final rule with comment period (78 FR 43643 through 43644 and 75090 through 75091).

b. Delayed Data Collection for OP–31 and Proposed Exclusion from the CY 2016 Payment Determination Measure Set

Since our adoption of this measure, we have come to believe that it may be operationally difficult for hospitals to collect and report this measure. Specifically, we are concerned that the results of the survey used to assess the pre-operative and post-operative visual function of the patient may not be shared across clinicians, making it difficult for hospitals to have knowledge of the visual function of the patient before and after surgery.

We are also concerned about the use of inconsistent surveys to assess visual function; the measure specifications allow for the use of any validated survey and results may be inconsistent should clinicians use different surveys. Therefore, on December 31, 2013, we issued guidance stating that we would delay the implementation of OP–31 by 3 months from January 1, 2014 to April 1, 2014 for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228721506778*). Because of continuing concerns, on April 2, 2014, we issued additional guidance stating that we would further delay the implementation of the measure from April 1, 2014 to January 1, 2015 for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228721506778*). Therefore, we are proposing to exclude OP–31 Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) from the CY 2016 payment determination measure set. We will not subject hospitals to a payment reduction with respect to this measure for the CY 2016 payment determination.

We invite comment on this proposal.

c. Proposed Voluntary Collection of Data for OP–31 for the CY 2017 Payment Determination and Subsequent Years

We continue to believe that this measure addresses an area of care that is not adequately addressed in our current measure set and that the measure serves to drive coordination of care (78 FR 75103). Further, we believe that HOPDs should be a partner in care with physicians and other clinicians using their facility, and this measure provides an opportunity to do so. Therefore, we are continuing to include this measure in the Hospital OQR Program measure set, but we are proposing that hospitals have the option to voluntarily collect and submit OP–31 data for the CY 2015 encounter period/CY 2017 payment determination and subsequent years. Further, we will not subject hospitals to a payment reduction with respect to this measure during the period of voluntary reporting. For hospitals that choose to voluntarily submit data, we would request that they submit such data using the means and timelines finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75113). Data submitted voluntarily will be publicly reported as discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43645) and final rule (78 FR 75092).

We invite public comment on this proposal.

E. Proposed New Quality Measure for the CY 2017 Payment Determination and Subsequent Years

We are proposing to adopt one new claims-based measure into the Hospital OQR Program for the CY 2017 payment determination and subsequent years: OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Colonoscopy is one of the most frequently performed procedures in the outpatient setting in

the United States.[1] The most recent data available indicate that, in 2002 alone, physicians performed an estimated 14 million colonoscopies in the United States.[2] Colonoscopies are associated with a range of well-described and potentially preventable adverse events that can lead to hospital visits, repeat procedures, or surgical intervention for treatment, including colonic perforation, gastrointestinal (GI) bleeding, and cardiopulmonary events such as hypoxia, aspiration pneumonia, and cardiac arrhythmias. While hospital visits are generally unexpected after outpatient colonoscopy, the literature suggests that the majority of these visits occur within the first 7 days.[3 4 5] Reported hospital visit rates after outpatient colonoscopy range from 0.8 to 1.0 percent at 7 to 14 days post procedure, and from 2.4 to 3.8 percent at 30 days post procedure.[6 7 8] Some adverse events such as bleeding occur after the 7th day, but based on input from clinical experts, public comment, and empirical analyses, we concluded that unplanned hospital visits within 7 days is the optimal outcome to ensure capture of procedure-related adverse events and to minimize capture of hospital visits unrelated to the procedure. This measure provides the opportunity for providers to improve quality of care and to lower the rates of adverse events leading to hospital visits after outpatient colonoscopy; this will encourage providers to achieve the outcome rates of the best performers.

We believe it is important to reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care. Therefore, we are proposing to include OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, which is based on Medicare FFS claims, in the Hospital OQR Program for the CY 2017 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time because transparency in publicly reporting measure scores will make patient unplanned hospital visits (emergency department visits, observation stays, and inpatient admissions) following colonoscopies more visible to providers and patients and encourage providers to incorporate quality improvement activities in order to reduce these visits. Providers are often unaware of complications following colonoscopy for which patients visit the hospital.[9] This risk-standardized quality measure will address this information gap and promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates and variation across facilities in unplanned hospital visits after colonoscopy.

The outcome measured in the OP–32 measure is all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure. The measure score, also referred to as the facility-level risk-standardized hospital visit rate, is derived from the calculation of the ratio of the numerator to the denominator multiplied by the crude rate. The numerator is the number of predicted (meaning adjusted actual) hospital visits, which is the number of unplanned hospital visits within seven days of colonoscopy that the facility is predicted to have based on its case-mix. The denominator is the number of expected hospital visits, which is the number of unplanned hospital visits the facility is expected to have based on the nation's performance with the facility's case-mix. The crude rate is the national unadjusted number of patients who had a hospital visit post-colonoscopy among all patients who had a colonoscopy.

Based on discussions with clinical and technical panel experts, the measure excludes colonoscopies for patients undergoing concomitant high-risk upper GI endoscopy because these patients are at a higher risk for hospital visits than patients undergoing a typical colonoscopy, and patients with a history of inflammatory bowel disease (IBD) or diverticulitis in the year preceding the colonoscopy because we likely could not fully characterize and adjust for their pre-procedure risk of needing a post-procedure hospital visit or identify whether these admissions are planned or unplanned. The measure also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the 1 month after the procedure to ensure all patients have complete data available for outcome assessment. The statistical risk adjustment model includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following colonoscopy. Additional methodology details and information obtained from public comments for measure development are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

Section 1890A(a)(2) of the Act outlines the pre-rulemaking process established under section 1890A of the Act, which requires the Secretary to make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering. This measure was included on a publicly available document titled ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs'' on the NQF Web site at: *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx* (formerly referred to as the ''List of Measures Under Consideration'') in compliance with section 1890A(a)(2) of the Act. (We note that at the time the measure was listed on the ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs,'' it was named ''High-Acuity Care Visits after Outpatient Colonoscopy Procedure''.)

The MAP, which represents stakeholder groups, conditionally supported the measure, ''noting the need to provide outcome information to inform consumer decisions and drive quality improvement.'' The MAP further stated that ''[t]his measure addresses an important quality and safety issue with

[1] Russo A, Elixhauser A, Steiner C, Wier L. Hospital-Based Ambulatory Surgery, 2007: Statistical Brief #86. *Healthcare Cost and Utilization Project (HCUP) Statistical Briefs.* Rockville (MD) 2006.

[2] Seeff LC, Richards TB, Shapiro JA, et al. How many endoscopies are performed for colorectal cancer screening? Results from CDC's survey of endoscopic capacity. *Gastroenterology.* Dec 2004;127(6):1670–1677.

[3] Rathgaber SW., Wick TM. Colonoscopy completion and complication rates in a community gastroenterology practice. *Gastrointest Endosc.* 2006; 64:556–62.

[4] Rabeneck L, Saskin R, Paszat LF. Onset and clinical course of bleeding and perforation after outpatient colonoscopy: a population-based study. *Gastrointest Endosc.* 2011; 73:520–3.

[5] Ko CW, Riffle S, Michael L, et al. Serious complications within 30 days of screening and surveillance colonoscopy are uncommon. *Clin Gastroenterol Hepatol.* 2010; 8:166–73.

[6] Ko CW, Riffle S, Shapiro JA, et al. Incidence of minor complications and time lost from normal activities after screening or surveillance colonoscopy. *Gastrointest Endosc.* Apr 2007;65(4):648–656.

[7] Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* Oct 25 2010;170(19):1752–1757.

[8] Chukmaitov AS, Menachemi N, Brown SL, Saunders C, Tang A, Brooks R. Is there a relationship between physician and facility volumes of ambulatory procedures and patient outcomes? *J Ambul Care Manage.* Oct–Dec 2008;31(4):354–369.

[9] Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* Oct 25 2010;170(19):1752–1757.

incidence of these events ranging from 10 to 22 per 1,000 after risk adjustment.'' The MAP, however, also ''recognized the need for the measure to be further developed and gain NQF endorsement. [The] MAP expects the endorsement process to resolve questions of the reliability and validity of the measure as well as with the accuracy of the algorithm for attributing claims data in light of possible effects of the Medicare 3-day payment window policy.'' As required under section 1890A(a)(4) of the Act, we considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital OQR Program.

We believe we have addressed the concerns raised by the MAP to the extent possible. The measure is well defined and precisely specified for consistent implementation within and between organizations that will allow for comparability. Reliability testing demonstrated the measure data elements produced were repeatable; that is, the same results were produced a high proportion of the time when assessed in the same population in the same time period. Validity testing demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and that adequately identify differences in quality. In order to ensure the accuracy of the algorithm for attributing claims data and the comprehensive capture of HOPD colonoscopies potentially affected by the policy, we identified physician claims for colonoscopy in the HOPD setting from the Medicare Part B Standard Analytical Files (SAF) with an inpatient admission within three days and lacking a corresponding HOPD facility claim. We then attribute the colonoscopies identified as affected by this policy to the appropriate HOPD facility using the facility provider ID from the inpatient claim.

Section 1833(t)(17)(C)(i) of the Act states that, ''The Secretary shall develop measures . . . that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.'' We believe that this proposed measure reflects consensus among the affected parties, because the MAP, which represents stakeholder groups, reviewed, conditionally supported the measure, and stated that it ''would provide valuable outcome information to inform consumer decision and drive quality improvement.'' Further, the measure was subject to public comment during the MAP and measure development processes, with some public commenters agreeing with the MAP's conclusions on the measure (p. 184, MAP Report, January 2014; *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*). We also note that the measure was submitted to NQF for endorsement on February 21, 2014.

Currently, there are no publicly available quality of care reports for providers or facilities that conduct outpatient colonoscopies. Thus, adoption of this measure provides an opportunity to enhance the information available to patients choosing among providers who offer this elective procedure. We believe this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to providers and patients all unplanned hospital visits following the procedure. Further, providing outcome rates to providers will make visible to clinicians meaningful quality differences and encourage improvement. Although this measure is not NQF-endorsed, it is currently undergoing the endorsement process, as noted above. Thus, we believe the statutory requirement for included measures to have, to the extent feasible and practicable, been set forth by a national consensus-building entity has been met by the measure being proposed for adoption.

We invite public comment on the proposal to include the following measure in the Hospital OQR Program for the CY 2017 payment determination and subsequent years.

NQF No.	Proposed measure for the CY 2017 payment determination and subsequent years
Pending	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

The proposed and previously finalized measures are listed below.

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
N/A	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.****
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0289	OP–5: Median Time to ECG.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.
N/A	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP–22: ED—Left Without Being Seen.****

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF No.	Measure name
0661	OP–23: ED—Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients.
0659	OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**
N/A	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.***

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889963089&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D1r_OP26MIF_v+6+0b.pdf&blobcol=urldata&blobtable=MungoBlobs*.

** Measure we are proposing for voluntary data collection in section XIII.D.3.b. of this proposed rule.

*** New measure proposed for the CY 2017 payment determination and subsequent years.

**** Name has been updated to correspond with NQF-endorsed name.

F. Possible Hospital OQR Program Measures and Topics for Future Consideration

The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, the use of health information technology (health IT), care coordination, patient safety, and volume. For future payment determinations, we are considering expanding these measure areas and creating measures in new areas. Specifically, we are exploring (1) electronic clinical quality measures; (2) partial hospitalization measures; (3) behavioral health measures; and (4) other measures that align with the National Quality Strategy and the CMS Quality Strategy domains.

1. Electronic Clinical Quality Measures

HHS believes all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (HHS August 2013 Statement, ''Principles and Strategies for Accelerating Health Information Exchange.'' (*http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*)) The Department is committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (health IT) across the broader care continuum through a number of initiatives including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and HIE services through Medicare and Medicaid payment policies; (2) adoption of common standards and certification requirements for interoperable health IT; (3) support for privacy and security of patient information across all HIE-focused initiatives; and (4) governance of health information networks.

More information on the governance of health information networks and its role in facilitating interoperability of health information systems can be found at: *http://www.healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf*.

These initiatives are designed to encourage HIE among health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs as well as those who are not eligible for those programs, and are designed to improve care delivery and coordination across the entire care continuum. For example, the Transition of Care Measure #2 in Stage 2 of the Medicare and Medicaid EHR Incentive Programs requires HIE to share summary records for more than 10 percent of care transitions. In addition, to increase flexibility in the Office of the National Coordinator for Health Information Technology's (ONC's) health IT Certification Program and expand health IT certification, ONC has issued a proposed rule concerning a voluntary 2015 Edition of EHR certification criteria, which would more easily accommodate the certification of health IT used in health care settings where health care providers are not typically eligible for incentive payments under the EHR Incentive Programs, to facilitate greater HIE across the entire care continuum.

We believe that HIE and the use of certified EHRs can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of electronically specified clinical quality measures (eCQMs). More information on the Voluntary 2015 Edition EHR Certification Criteria proposed rule can be found at: *http://healthit.gov/policy-researchers-implementers/standards-and-certification-regulations*.

We anticipate that as electronic health records (EHR) technology evolves and more infrastructure is operational, we will begin to accept electronic reporting of many measures from EHR technology certified under the ONC health IT Certification Program. We are working diligently toward this goal. We believe that this progress would significantly reduce the administrative burden on hospitals under the Hospital OQR Program to report chart-abstracted measures. We recognize that considerable work needs to be done by measure owners and health IT developers and implementers to make this possible with respect to the clinical quality measures targeted for electronic specifications (e-specifications). This work includes completing e-specifications for measures, pilot testing, reliability and validity testing, and implementing such specifications in certified EHR technology to capture and calculate the results.

2. Partial Hospitalization Program Measures

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the hospital outpatient setting. Therefore, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75106), we stated that,

through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in hospital outpatient settings, such as partial hospitalization programs (PHPs) that are part of HOPDs.

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients as an alternative to inpatient psychiatric care for individuals who have acute mental illness. The PHP was designed to assist individuals with acute psychiatric illness in managing debilitating symptoms and prevent the need for hospitalization or re-hospitalization. Behavioral health treatments and services have improved and evolved through medication advances, recovery-based therapy, and evidenced-based interventions, including peer supports. PHP services have had the opportunity to evolve to provide individuals with a unique setting that can contribute to maintaining social and community connectivity while focusing on sustained recovery to prevent initial hospitalization during a given episode and subsequent re-hospitalization. Currently, the Hospital OQR Program has not adopted measures applicable to PHPs.

Although we believe that the PHP is an important program offering an alternative to inpatient stays, we note that PHP utilization has been declining.[10] Therefore, as we consider implementing PHP measures in future years, we invite public comment regarding the utility of including measures for this care setting in the Hospital OQR Program.

We specifically request public comment on three PHP measures we submitted to the MAP for consideration as part of the ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs'' (*http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx* (formerly referred to as the ''List of Measures Under Consideration'')):

- 30-Day Readmission;
- Group Therapy; and
- No Individual Therapy.

These measures are included in the Program for Evaluating Payment Patterns Electronic Reports (PEPPERs) developed under the Comprehensive Error Rate Testing (CERT) Program. Further information on these claims-based measures that provide indicators of quality of care can be found at *http://www.pepperresources.org/LinkClick.aspx?fileticket=stK9uUmQWlM%3d&tabid=148*.

We also request public input on other possible quality measures for partial hospitalization services for inclusion in the Hospital OQR Program in future years.

3. Behavioral Health Measures

In addition to PHP measures, we are considering other measures specific to behavioral health in the outpatient setting, including measures addressing depression and alcohol abuse. Major depression is a leading cause of disability in the United States, complicates the treatment of other serious illnesses, and is associated with an increased risk of suicide. Major depression is a common mental health condition, affecting 6 to 9 percent of those over 55 years of age.[11] Along with other serious mental health conditions, it has a higher Medicare inpatient readmission rate than all other conditions with the exception of heart failure.[12] Alcohol use disorders are the most prevalent type of addictive disorder in individuals ages 65 and over.[13] Roughly 6 percent of the elderly are considered to be heavy users of alcohol.[14] Alcohol abuse is often associated with depression and contributes to the etiology of serious medical conditions, including liver disease and coronary heart disease. Because of the prevalence of depression and alcohol abuse and their impact on the Medicare population, we believe that we should consider measures in these and other behavioral health areas for use in future Hospital OQR Program payment determination years. Therefore, we invite public comment on measures applicable to these areas that would be suitable for the Hospital OQR Program.

4. National Quality Strategy and CMS Quality Strategy Measure Domains

In considering future Hospital OQR Program measures, we are focusing on the following National Quality Strategy and CMS Quality Strategy measure domains: Making care safer, strengthen person and family engagement, promote effective communication and coordination of care, promote effective prevention and treatment, work with communities to promote best practices of healthy living, and make care affordable. We believe measures in these areas will promote better care and align measures across multiple CMS quality programs, in particular, the Hospital OQR, Hospital IQR, and ASCQR Programs.

We invite public comment on these possible measures.

G. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital Outpatient Quality Reporting (OQR) Program Requirements for the CY 2015 Payment Update

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on the measures selected by the Secretary, in the form and manner, and at a time, required by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent payment year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative

[10] *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Leung_PHP_PPS_2010.pdf*.

[11] O'Connor E, Whitlock E, Beil T, et al. Screening for depression in adult patients in primary care settings: a systematic evidence review. Annals of Internal Medicine 2009 December 1:151(11):793–803.

[12] Stephen F. Jencks, M.D., M.P.H., Mark V. Williams, M.D., and Eric A. Coleman, M.D., M.P.H. Rehospitalizations among Patients in the Medicare Fee-for-Service Program. N Engl J Med 2009;360:1418–28.

[13] Stephen Ross. Alcohol Use Disorders in the Elderly. Psychiatry Weekly (no date) Available at: *http://www.psychweekly.com/aspx/article/ArticleDetail.aspx?articleid=19*.

[14] AL Mirand and JW Welte. Alcohol consumption among the elderly in a general population, Erie County, New York. Am J Public Health. 1996 July; 86(7): 978–984.

payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site): ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' or ''U.'' We note that we are proposing to delete status indicator ''X''' as described in sections II.A.3. and X. of this proposed rule. We also note that we are proposing to develop status indicator ''J1'' as part of our comprehensive APC policy, effective for CY 2015, discussed in section II.A.2.e. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910) and section II.A.2.e. of this proposed rule. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T.'' We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2015

We are proposing to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2015 annual payment update factor. For the CY 2015 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of $72.692 by the proposed full conversion factor of $74.176. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2015 OPPS, we are proposing to apply the reporting ratio, when applicable, to all HCPCS codes to which we have assigned status indicators ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' and ''U'' (other than new technology APCs to which we have assigned status indicators ''S'' and ''T''). We note that we are proposing to delete status indicator ''X'' as described in sections II.A.3. and X. of this proposed rule. We note that we are proposing to develop status indicator ''J1'' as part of our CY 2015 comprehensive APC policy, discussed in section II.A.2.e. of this proposed rule and to apply the reporting ratio to the comprehensive APCs. We are proposing to continue to exclude services paid under New Technology APCs. We are proposing to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also are proposing to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we are proposing to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We invite public comment on these proposals.

H. Proposed Requirements for Reporting Hospital OQR Program Data for the CY 2017 Payment Determination and Subsequent Years

1. Administrative Requirements for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) for a discussion of the Hospital OQR Program procedural requirements for the CY 2015 payment determination and subsequent years. In that final rule with comment period, we codified these procedural requirements at 42 CFR 419.46(a).

2. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

a. General Procedural Requirements

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 through 75111) for a discussion of Hospital OQR Program general procedural requirements. In that final rule with comment period, we finalized our proposal to codify these general procedural requirements at 42 CFR 419.46(c).

We are proposing to correct a typographical error in 42 CFR 419.46(c). This section states, ''Except as provided in paragraph (d) of this section, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(17)(C) of the Act . . '' We are proposing to correct the erroneous reference of ''section 1833(17)(C)'' to ''section 1833(t)(17)(C).'' We invite public comment on this proposal.

b. Requirements for Chart-Abstracted Measures Where Data Is Submitted Directly to CMS for the CY 2017 Payment Determination and Subsequent Years

The following chart-abstracted measures in the Hospital OQR Program require data to be submitted for the CY 2017 payment determination and subsequent years:

- OP–1: Median Time to Fibrinolysis;
- OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- OP–5: Median Time to ECG (NQF #0289);
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496);
- OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional;
- OP–21: ED—Median Time to Pain Management for Long Bone Fracture (NQF #0662);
- OP–22: ED—Left Without Being Seen;
- OP–23: ED—Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 Minutes of Arrival (NQF #0661);
- OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); and
- OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #1536).

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form and manner for data submission of these measures.

We are neither proposing new chart-abstracted measures where patient-level data is submitted directly to CMS nor proposing new requirements for data submission for chart-abstracted measures.

c. Claims-Based Measure Data Requirements for the CY 2017 Payment Determination and Subsequent Years

As discussed in section XIII.E. of the preamble of this proposed rule, we are proposing one additional claims-based measure for the CY 2017 payment determination and subsequent years, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. If this proposal is finalized, there will be a total of eight claims-based measures for the CY 2017 payment determination and subsequent years:

- OP–8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP–9: Mammography Follow-Up Rates;
- OP–10: Abdomen CT—Use of Contrast Material;
- OP–11: Thorax CT—Use of Contrast Material;
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (NQF #0669);
- OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT);
- OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache; and
- OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112) for a discussion of the claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years.

In the CY 2012 OPPS/ASC final rule with comment period, we deferred the public reporting of OP–15 (76 FR 74456). We extended the postponement of public reporting for this measure in the CY 2013 and CY 2014 OPPS/ASC final rules with comment period (77 FR 68481, 78 FR 75111). We are not proposing any changes to this policy. Public reporting for OP–15 continues to be deferred, and this deferral has no effect on any payment determinations; however, hospitals are still required to submit data as previously finalized (76 FR 74456).

d. Data Submission Requirements for Measure Data Submitted via the CMS Web-Based Tool for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115) for a discussion of the requirements for measure data submitted via the Web-based tool on a CMS Web site (the QualityNet Web site) for the CY 2016 payment determination and subsequent years.

We are not proposing any changes to the data submission requirements for data submitted via the CMS Web-based tool.

e. Population and Sampling Data Requirements for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our policy that hospitals may voluntarily submit aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted. We are not proposing any changes to this policy.

f. Proposed Review and Corrections Period for Chart-Abstracted Measures

Under the Hospital OQR Program, hospitals submit chart-abstracted data to CMS on a quarterly basis. This data is typically due 4 months after the quarter has ended, unless we grant an extension or exception, as further described in section XIII.J. of this proposed rule. We refer readers to the CY 2014 OPPS/ASC

final rule with comment period for a discussion of our previously finalized policies regarding submissions deadlines for chart-abstracted measures (78 FR 68482). Hospitals can begin submitting data on the first discharge day of any reporting quarter and can modify this data up until the close of the submission period (or 4 months after the quarter has ended). For example, if a hospital enters data on January 2, it could continue to review, correct, and change this data until August 1, the first quarter submission deadline. We generally provide rates for the measures that have been submitted for chart-abstracted, patient-level data 24–48 hours following submission. Hospitals are encouraged to submit data early in the submission schedule so that they can identify errors and resubmit data before the quarterly submission deadline.

We are proposing to formalize this 4-month period as the review and corrections period for chart-abstracted data for the Hospital OQR Program. During this review and corrections period, hospitals can enter, review, and correct data submitted directly to CMS. After the submission deadline, however, hospitals would not be allowed to change these data. We believe that 4 months is sufficient time for hospitals to perform these activities. We invite public comment on this proposal.

3. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2017 Payment Determination and Subsequent Years

a. Background

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487) for a discussion of finalized policies regarding our validation requirements. We codified these policies at 42 CFR 419.46(e). We are proposing three changes to our validation procedures: (1) We are proposing to change the eligibility requirements for hospitals selected for validation so that a hospital would be eligible if it submits at least one case to the Hospital OQR Program Clinical Data Warehouse during the quarter containing the most recently available data; (2) we are proposing give hospitals the option to either submit paper copies of patient charts or securely transmit electronic versions of medical information for validation; and (3) we are proposing that a hospital must identify the medical record staff responsible for submission of records under the Hospital OQR Program to the designated CMS contractor.

b. Proposed Selection of Hospitals for Data Validation of Chart-Abstracted Measures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2012 and CY 2013 OPPS/ASC final rules with comment period (76 FR 74484 through 74485 and 77 FR 68484 through 68485) for a discussion of finalized policies regarding our sampling methodology, including sample size, eligibility for validation selection, and encounter minimums for patient-level data for measures where data is obtained from chart abstraction and submitted directly to CMS from selected hospitals.

We are proposing one change to this process. Previously, to be eligible for random selection for validation, a hospital must have been coded as ''open'' in the CASPER system at the time of selection and must have submitted at least 10 encounters to the OPPS Clinical Warehouse during the data collection period for the applicable payment determination (76 FR 74484). We are proposing that, beginning with the CY 2015 encounter period for the CY 2017 payment determination and subsequent years, a hospital will be eligible for validation if it submits at least one case to the Hospital OQR Program Clinical Data Warehouse during the quarter containing the most recently available data. The quarter containing the most recently available data will be defined based on when the random sample is drawn. For example, if we draw a sample in December 2014, the most recent data available would be that from the second quarter of 2014, which ends June 2014, because the submission deadline for second quarter data would be November 1, 2014 (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1205442125082*; 78 FR 68482). As another example, if a sample is drawn in October 2014, the most recent available data would be from quarter one, which ended in March 2014, because data must be submitted by August 1, 2014. We believe this change is necessary because it increases the probability that selected hospitals have current data in the Warehouse to be validated. Previously, hospitals that did not have data from the current year available could still be selected for validation. We invite public comment on this proposal.

c. Targeting Criteria for Data Validation Selection for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68485 through 68486) for a discussion of our targeting criteria. We are not proposing any changes to these policies.

d. Methodology for Encounter Selection for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486) for a discussion of our methodology for encounter selection. We are not proposing any changes to this policy.

e. Proposed Medical Record Documentation Requests for Validation and Validation Score Calculation for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487) for a discussion of our previously finalized procedures for requesting medical record documentation for validation and validation score calculation. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118), we codified these procedures at 42 CFR 419.46(e)(1) and (e)(2). We are proposing two changes to these policies for the CY 2017 payment determination and subsequent years: (1) We are proposing to give hospitals the option to either submit paper copies of patient charts or securely transmit electronic versions of medical information for validation; and (2) we are proposing that a hospital must identify the medical record staff responsible for submission of records under the Hospital OQR Program to the designated CMS contractor.

For records stored electronically, hospitals expend additional resources printing records onto paper that may be more efficiently transmitted electronically. In addition, the length of paper charts has been increasing, and the paper used to submit these records has an environmental impact. Therefore, we are proposing to give hospitals the option to either submit copies of paper patient charts or securely transmit electronic versions of medical information, which has the potential to significantly reduce administrative burden, cost, and environmental impact. We have already finalized a similar policy for the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50834 through 50836) that allows hospitals for the Hospital IQR Program to submit electronic records through the mail on a CD, DVD, or flash drive. In addition, in the FY 2015 IPPS/LTCH PPS proposed rule for the Hospital IQR Program (79 FR 28251), we have

proposed to also allow hospitals to submit patient charts using a Secure File Transfer Portal on the QualityNet Web site.

The current Hospital OQR Program regulation at § 419.46(e)(1) states: ''Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. . . .'' We are proposing that this requirement may be met by employing either of the following options for the CY 2017 payment determination and subsequent years: (1) A hospital may submit paper medical records, the form in which we have historically requested them; or (2) a hospital may securely transmit electronic versions of medical information.

For the CY 2017 payment determination and subsequent years, we are proposing that hospitals that chose to securely transmit electronic versions of medical information should either: (1) Download or copy the digital image of the patient chart onto CD, DVD, or flash drive and ship the electronic media following instructions specified on the QualityNet Web site; or (2) securely submit digital images (PDFs) of patient charts using a Secure File Transfer Portal on the QualityNet Web site. The Secure File Transfer Portal would allow hospitals to transfer files through either a Web-based portal or directly from a client application using a secure file transfer protocol. The system provides a mechanism for securely exchanging documents containing sensitive information such as Protected Health Information (PHI) or Personally Identifiable Information (PII). Detailed instructions on how to use this system are available in the Secure File Transfer 1.0 User Manual available on QualityNet at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228773343598*.

In addition, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487), we stated that our validation contractor would request medical documentation from each hospital selected for validation via certified mail or other trackable method. This request would be sent to ''the hospital's medical record staff identified by the hospital for the submission of records under the Hospital IQR Program (that is, the hospital's medical records staff identified by the hospital to the State QIO)'' (77 FR 68487). Quality Improvement Organizations (QIOs) are CMS contractors required by the Act (section 1152 through 1154) tasked with, among other responsibilities, assisting hospitals with quality improvement activities. Due to the evolution of the structure of the QIO program, beginning with CY 2015 for the CY 2017 payment determination and subsequent years, we are proposing that a hospital must identify the medical record staff responsible for submission of records under the Hospital OQR Program to the designated CMS contractor; this CMS contractor may be a contractor other than the State QIO.

Finally, we note that a typographical error exists in our validation language in § 419.46(e). This section states, ''CMS may validate one or more measures selected under section 1833(17)(C) of the Act . . .'' ''[S]ection 1833(17)(C)'' should instead state ''section 1833(t)(17)(C).'' We are proposing to make this change in the regulation text.

We invite public comment on these proposals.

I. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119) for a discussion of our reconsideration and appeals procedures. We codified this process by which participating hospitals may submit requests for reconsideration at 42 CFR 419.46(f). We also codified language at § 419.46(f)(3) stating that a hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board.

We are not proposing any changes to the reconsideration and appeals procedures.

J. Extension or Exception Process for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances extension or waiver process under the Hospital OQR Program. We are not proposing any substantive changes to these policies or the processes.

However, in the future, we will refer to the process as the Extraordinary Circumstances Extensions or Exemptions process, instead of the Extraordinary Circumstances Extensions or Waiver process. We are in the process of revising the Extraordinary Circumstances/Disaster Extension or Waiver Request form (CMS–10432), approved under OMB control number 0938–1171. We are updating the forms and instructions so that a hospital or facility may apply for an extension for all applicable quality reporting programs at one time.

In addition, we are proposing to make a conforming change from the phrase ''extension or waiver'' to the phrase ''extension or exemption'' in 42 CFR 419.46(d). Section 419.46(d) currently states,

Exception. CMS may grant an extension or waiver of one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an extension or waiver as follows:

(1) *Upon request by the hospital.* Specific requirements for submission of a request for an extension or waiver are available on the QualityNet Web site.

(2) *At the discretion of CMS.* CMS may grant waivers or extensions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

We are proposing to revise this language to state,

Exception. CMS may grant an extension or exception of one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an extension or exception as follows:

(1) *Upon request by the hospital.* Specific requirements for submission of a request for an extension or exception are available on the QualityNet Web site.

(2) *At the discretion of CMS.* CMS may grant exceptions or extensions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIII.A.1. of this proposed rule for a general overview of our quality reporting programs.

2. Statutory History of the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

We refer readers to section XIV.K.1. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to section XV.A.3. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75122) for an overview of the regulatory history of the ASCQR Program.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of priorities we consider for ASCQR Program quality measure selection.

2. Proposed Policy for Removal of Quality Measures From the ASCQR Program

We previously adopted a policy to retain measures from the previous year's ASCQR Program measure set for subsequent years' measure sets except when they are removed, suspended or replaced as indicated (76 FR 74504; 77 FR 68494 through 68495; 78 FR 75122). In this proposed rule, we are proposing a process for removing adopted measures.

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43863 through 43865), we finalized a process for immediate retirement (a term we later changed to ''removal'') of RHQDAPU Program (now referred to as the Hospital IQR Program) measures based on evidence that the continued use of the measure as specified raised patient safety concerns. We stated that we believe immediate retirement of quality measures should occur when the clinical evidence suggests that continued collection of the data may result in harm to patients. For example, we removed the AMI–6-Beta Blocker at Arrival measure from the Hospital IQR Program because it encouraged care that raised potential safety concerns according to newly published research suggesting that beta-blockers could increase mortality risks for certain patient populations (74 FR 43863). Under such circumstances, we may not be able to wait until the annual rulemaking cycle or until we have had the opportunity to obtain input from the public to retire the measure because of the need to discourage potentially harmful practices which may result from continued collection of the measure.

In these situations, we would promptly retire the measure and notify hospitals and the public of the retirement of the measure and the reasons for its retirement through the usual communication channels. Further, we would confirm the retirement of the measure that was the subject of immediate retirement in the next program rulemaking. Finally, we stated that, in other circumstances where we do not believe that continued use of a measure raises specific safety concerns, we intend to use the rulemaking process to retire a measure. For the same reasons stated for the Hospital IQR Program, we believe that this process also would be appropriate for the ASCQR Program. Therefore, we are proposing to adopt this same removal process for the ASCQR Program. Under this process, we would immediately remove an ASCQR Program measure based on evidence that the continued use of the measure as specified raised patient safety concerns. In these situations, we would promptly remove the measure and notify ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR Program ListServ and the ASCQR Program QualityNet Web site at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772879650*. Further, we would confirm the removal of the measure that was the subject of immediate removal in the next OPPS/ASC rulemaking.

For situations where we do not believe that continued use of a measure raises specific safety concerns, we are proposing to use the regular rulemaking process to remove a measure to allow for public comment. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53505 through 53506), we listed the criteria we have used to determine whether to remove measures from the Hospital IQR Program. These criteria are: (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); (2) availability of alternative measures with a stronger relationship to patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. These criteria were suggested through public comment on proposals for the Hospital IQR Program and, we agreed that these criteria should be considered in evaluating the Hospital IQR Program quality measures for removal (75 FR 53506). We believe that these criteria also are applicable in evaluating ASCQR Program quality measures for removal, because we have found them useful for evaluating measures in the Hospital IQR Program and our other quality reporting programs, which share similar goals to the ASCQR Program. Accordingly, we are proposing to adopt these measure removal criteria for the ASCQR Program.

We invite public comment on these proposals.

3. Proposed Criteria for Removal of ''Topped-Out'' Measures

We are proposing to define criteria for when we would consider a measure to be ''topped-out.'' A measure is ''topped-out'' when measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures). We do not believe that measuring ASC performance on ''topped-out'' measures provides meaningful information on the quality of care provided by ASCs. We further believe that quality measures, once ''topped-out,'' represent care standards that have been widely adopted by ASCs. We believe such measures should be considered for removal from the ASCQR Program because their associated reporting burden may outweigh the value of the quality information they provide.

Specifically, we are proposing that a measure under the ASCQR Program is ''topped-out'' when it meets both of the following criteria:

- Statistically indistinguishable performance at the 75th and 90th percentiles; and
- A truncated coefficient of variation less than or equal to 0.10.

To identify if a measure has statistically indistinguishable performance at the 75th and 90th percentiles, we would determine whether the difference between the 75th and 90th percentiles for an ASC's measure is within two times the standard error of the full dataset. The coefficient of variation (CV) is a descriptive statistic that expresses the standard deviation as a percentage of the sample mean; this provides a

statistic that is independent of the units of observation. Applied to this analysis, a large CV would indicate a broad distribution of individual ASC scores, with large and presumably meaningful differences between ASCs in relative performance. A small CV would indicate that the distribution of individual hospital scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions among individual ASCs' measure performance. The truncated CV excludes observations whose rates are below the 5th percentile and above the 95th percentile. This was done to avoid undue effects of the highest and lowest outlier ASCs, which if included, would tend to greatly widen the dispersion of the distribution and make the measure appear to be more reliable or discerning. These same criteria for when we would consider a measure to be ''topped-out'' have been proposed for adoption in the Hospital VBP Program (79 FR 28119) and the Hospital IQR Program (79 FR 28219).

We invite public comment on this proposal.

4. ASCQR Program Quality Measures Adopted in Previous Rulemaking

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination. In the CY 2012 OPPS/ASC final rule with comment period, we adopted five claims-based measures for the CY 2014 payment determination and subsequent years, two measures with data submission via an online Web page for the CY 2015 payment determination and subsequent years, and one process of care measure for the CY 2016 payment determination and subsequent years (74 FR 74496 to 74511). In the CY 2014 OPPS/ASC final rule with comment period, we adopted three chart-abstracted measures for the CY 2016 payment determination and subsequent years (78 FR 75124 to 75130).

The quality measures that we have previously adopted are listed below.

ASC Program Measure Set Previously Adopted for the CY 2016 Payment Determination and Subsequent Years

ASC No.	NQF No.	Measure name
ASC–1	0263	Patient Burn.
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	0265	Hospital Transfer/Admission.
ASC–5	0264	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6	N/A	Safe Surgery Checklist Use.
ASC–7	N/A	ASC Facility Volume Data on Selected ASC Surgical Procedures. Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754*.
ASC–8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC–9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
ASC–11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.*

*We are proposing voluntary data collection starting in CY 2017 for this previously adopted measure in section XIV.E.3.c. of this proposed rule.

5. Proposed New ASCQR Program Quality Measure for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124) for a detailed discussion of our approach to ASCQR measure selection. In this proposed rule, we are proposing to adopt one new claims-based measure into the ASCQR Program for the CY 2017 payment determination and subsequent years: ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

Colonoscopy is the most commonly performed ambulatory surgery in the United States.[15] The most recent data available indicate that, in 2002 alone, physicians performed an estimated 14 million colonoscopies in the United States.[16] Colonoscopies are associated with a range of well-described and potentially preventable adverse events that can lead to hospital visits, repeat procedures, or surgical intervention for treatment, including colonic perforation, gastrointestinal (GI) bleeding, and cardiopulmonary events such as hypoxia, aspiration pneumonia, and cardiac arrhythmias. While hospital visits are generally unexpected after outpatient colonoscopy, the literature suggests that the majority of these visits occur within the first 7 days.[17] [18] [19] Reported hospital visit rates after outpatient colonoscopy range from 0.8 to 1.0 percent at 7 to 14 days post procedure, and from 2.4 to 3.8 percent at 30 days post procedure.[20] [21] [22] Some adverse events such as bleeding occur after day 7, but based on input from clinical experts, public comment, and

[15] Russo A, Elixhauser A, Steiner C, Wier L. Hospital-Based Ambulatory Surgery, 2007: Statistical Brief #86. *Healthcare Cost and Utilization Project (HCUP) Statistical Briefs.* Rockville (MD)2006.

[16] Seeff LC, Richards TB, Shapiro JA, et al. How many endoscopies are performed for colorectal cancer screening? Results from CDC's survey of endoscopic capacity. *Gastroenterology.* Dec 2004;127(6):1670–1677.

[17] Rathgaber SW, Wick TM. Colonoscopy completion and complication rates in a community gastroenterology practice. *Gastrointest Endosc.* 2006; 64:556–62.

[18] Rabeneck L, Saskin R, Paszat LF. Onset and clinical course of bleeding and perforation after outpatient colonoscopy: A population-based study. *Gastrointest Endosc.* 2011; 73:520–3.

[19] Ko CW, Riffle S, Michael L, et al. Serious complications within 30 days of screening and surveillance colonoscopy are uncommon. *Clin Gastroenterol Hepatol.* 2010; 8:166–73.

[20] Ko CW, Riffle S, Shapiro JA, et al. Incidence of minor complications and time lost from normal activities after screening or surveillance colonoscopy. *Gastrointest Endosc.* Apr 2007;65(4):648–656.

[21] Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* Oct 25 2010;170(19):1752–1757.

[22] Chukmaitov AS, Menachemi N, Brown SL, Saunders C, Tang A, Brooks R. Is there a relationship between physician and facility volumes of ambulatory procedures and patient outcomes? *J Ambul Care Manage.* Oct-Dec 2008;31(4):354–369.

empirical analyses, we concluded that unplanned hospital visits within 7 days is the optimal outcome to ensure capture of procedure-related adverse events and to minimize capture of hospital visits unrelated to the procedure. This measure provides the opportunity for ASCs to improve quality of care and to lower the rates of adverse events leading to hospital visits after outpatient colonoscopy; this would encourage ASCs to achieve the outcome rates of the best performers.

We believe it is important to reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care. Therefore, we are proposing to include the ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, which is based on Medicare FFS claims, in the ASCQR Program for the CY 2017 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time because transparency in publicly reporting measure scores would make patient unplanned hospital visits (emergency department visits, observation stays and inpatient admissions) following colonoscopies more visible to ASCs and patients and incentivize ASCs to incorporate quality improvement activities in order to reduce these visits. ASCs are often unaware of complications following colonoscopy for which patients visit the hospital.[23] This risk-standardized quality measure would address this information gap and promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates and variation across facilities in unplanned hospital visits after colonoscopy.

The outcome measured in the ASC–12 measure is all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure. The measure score, also referred to as the facility-level risk-standardized hospital visit rate, is derived from the calculation of the ratio of the numerator to the denominator multiplied by the crude rate. The numerator is the number of predicted (meaning adjusted actual) hospital visits, which is the number of unplanned hospital visits within seven days of colonoscopy that the facility is predicted to have based on its case-mix. The denominator is the number of expected hospital visits, which is the number of unplanned hospital visits the facility is expected to have based on the nation's performance with the facility's case-mix. The crude rate is the national unadjusted number of patients who had a hospital visit post-colonoscopy among all patients who had a colonoscopy.

Based on discussions with clinical and technical panel experts, the measure excludes colonoscopies for patients undergoing concomitant high-risk upper GI endoscopy because these patients are at a higher risk for hospital visits than patients undergoing a typical colonoscopy, and patients with a history of inflammatory bowel disease (IBD) or diverticulitis in the year preceding the colonoscopy because we likely could not fully characterize and adjust for their pre-procedure risk of needing a post-procedure hospital visit or identify whether these admissions are planned or unplanned. The measure also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the first month after the procedure to ensure all patients have complete data available for outcome assessment. The statistical risk adjustment model includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within seven days following a colonoscopy. Additional methodology details, and information obtained from public comment for measure development are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Section 1890A of the Act requires the Secretary to establish a pre-rulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1st of each year a list of quality and efficiency measures that the Secretary is considering for the Medicare program. The measure that we are proposing was reviewed by the MAP and was included on a publicly available document entitled ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs'' (formerly referred to as the ''List of Measures Under Consideration'') on the NQF Web site at: *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx* (''MAP Report''). (We note that at the time the measure was listed on the ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs'' it was named, ''High-Acuity Care Visits after Outpatient Colonoscopy Procedure.'') The MAP conditionally supported this measure for the ASCQR Program.

The MAP Report stated that the measure ''[s]hould be submitted for and receive NQF endorsement; Measure is promising but needs further development,'' (p. 187, MAP Report). Further, the MAP Report stated that the measure ''would provide valuable outcome information to inform consumer decision and drive quality improvement'' and that the ''NQF endorsement process would resolve questions about the reliability and validity of the measure.'' The MAP also stated that NQF endorsement would resolve questions about ''the feasibility of the algorithm for attributing claims data in light of possible effects of the Medicare three-day payment window'' (p. 187, MAP Report). However, this concern with Part A hospital payments relates to the Hospital OQR Program and not the ASCQR Program. As required under section 1890A(a)(4) of the Act, we considered the input and recommendations provided by the MAP in selecting measures to propose for the ASCQR Program.

We believe we have addressed the concerns raised by the MAP to the extent possible. The measure was submitted to NQF for endorsement on February 21, 2014. The measure is well-defined and precisely specified for consistent implementation within and between organizations that will allow for comparability. Reliability testing demonstrated the measure data elements produced were repeatable; that is, the same results were produced a high proportion of the time when assessed in the same population in the same time. Validity testing demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and that adequately identify differences in quality.

Currently, there are no publicly available quality of care reports for ASCs that conduct outpatient colonoscopies. Thus, adoption of this measure provides an opportunity to enhance the information available to patients choosing among ASCs who offer this elective procedure. We believe this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to ASCs and patients all unplanned hospital visits following the procedure.

[23] Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* Oct 25 2010;170(19):1752–1757.

In addition, providing outcome rates to ASCs would make visible to clinicians meaningful quality differences and incentivize improvement.

Sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, when read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. We believe this proposed measure meets these statutory requirements. We believe that this measure is appropriate for the measurement of quality of care furnished by ASCs because this procedure is commonly performed in ASCs and, as discussed above, can signify important issues in the care being provided in ASCs. We also believe this measure reflects consensus among affected parties, because the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure, and stated that it ''would provide valuable outcome information to inform consumer decision and drive quality improvement.'' Further, the measure was subject to public comment during the MAP and measure development processes, with some public commenters agreeing with the MAP's conclusions on the measure (p. 187, MAP Report, January 2014; *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*).

As discussed above, the statute also requires the Secretary, except as the Secretary may otherwise provide, to include measures set forth by one or more national consensus building entities to the extent feasible and practicable. This measure is not NQF-endorsed; however, as noted above, this measure is currently undergoing the NQF endorsement process. We note that section 1833(t)(17) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act, which contains this requirement, applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures.

In summary, we are proposing to adopt one new measure for the ASCQR Program for the CY 2017 payment determination and subsequent years.

ASC No.	NQF No.	Proposed ASCQR measure for the CY 2017 payment determination and subsequent years
ASC–12	Pending	Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

If this proposal is finalized, the measure set for the ASCQR Program CY 2017 payment determination and subsequent years would be as listed below.

PROPOSED ASC PROGRAM MEASURE SET FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	Measure name
ASC–1	0263	Patient Burn.
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	0265	Hospital Transfer/Admission.
ASC–5	0264	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6	N/A	Safe Surgery Checklist Use.
ASC–7	N/A	ASC Facility Volume Data on Selected ASC Surgical Procedures. Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754*.
ASC–8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC–9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
ASC–11.	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.*
ASC–12	Pending	Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.**

*We are proposing voluntary data collection for this previously adopted measure in section XIV.E.3.c. of this proposed rule.
**New measure proposed for CY 2017 payment determination and subsequent years.

We invite public comment on our proposal to include ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy in the ASCQR Program beginning with the CY 2017 payment determination.

6. ASCQR Program Measures for Future Consideration

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494), where we finalized our approach to future measure selection for the ASCQR Program. We seek to develop a comprehensive set of quality measures to be available for widespread use for informed ''patient decision-making and quality improvement in the ASC setting'' (77 FR 68496). We also seek to align these quality measures with the National Quality Strategy (NQS), the CMS Strategic Plan (which includes the CMS Quality Strategy), and our other quality reporting and value-based

purchasing programs, as appropriate. Accordingly, in considering future ASCQR Program measures, we are focusing on the following NQS and CMS Quality Strategy measure domains: Make care safer; strengthen person and family engagement; promote effective communication and coordination of care; promote effective prevention and treatment; work with communities to promote best practices of healthy living; and make care affordable.

7. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514), where we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures, including the subregulatory process for making updates to the adopted measures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68496 through 68497) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy, including the processes for addressing nonsubstantive and substantive changes to adopted measures.

We maintain technical specifications for previously adopted ASCQR Program measures. These specifications are updated as we continue to develop the ASCQR Program. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754*.

Many of the quality measures used in Medicare and Medicaid reporting programs are NQF-endorsed. We note that two of the measures previously adopted for the ASCQR Program are not NQF-endorsed, and NQF endorsement is not a program requirement. However, for those measures that are NQF-endorsed, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years as part of its regular maintenance process for NQF-endorsed performance measures. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes with the NQF on an annual basis. The NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific 3-year cycle.

We note that the NQF's annual or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to measures in order to maintain endorsement status. Other non-NQF measures may undergo maintenance changes as well. We believe that it is important to have in place the subregulatory process that we have adopted for the ASCQR Program to incorporate nonsubstantive updates into the measure specifications for measures so that the measure specifications remain current. We also recognize that some changes to measures are substantive in nature and might not be appropriate for adoption using a subregulatory process.

We are not proposing any changes to this policy.

8. Public Reporting of ASCQR Program Data

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. These data will be displayed at the CCN level. We are not proposing any changes to this policy.

C. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to section XV.C.1. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131 through 75132) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. Currently, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the MFP-adjusted CPI–U update factor, which is the adjustment set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted CPI–U update factor is the Consumer Price Index for all urban consumers (CPI–U), which currently is the annual update for the ASC payment system, minus the MFP adjustment. As discussed in the CY 2011 MPFS final rule with comment period (75 FR 73397), if the CPI–U is a negative number, the CPI–U would be held to zero. Under the ASCQR Program, any annual update would be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction would apply beginning with the CY 2014 payment rates. For a complete discussion of the calculation of the ASC conversion factor, we refer readers to section XII.G. of this proposed rule.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: A full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to this proposed rule, which are available via the Internet on the CMS Web site): ''A2,'' ''G2,'' ''P2,'' ''R2,'' ''Z2,'' as well as the service portion of device-intensive procedures identified by ''J8.'' We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor.

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2,'' ''G2,'' ''J8,'' ''P2,'' ''R2,'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS

payment rates, and certain office-based procedures and radiology services where payment is based on the MPFS PE RVU amount and a few other specific services that receive cost-based payment. As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update.

Office-based surgical procedures (performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.C.1.b. of this proposed rule) are paid at the lesser of the MPFS nonfacility PE RVU-based amounts and the standard ASC ratesetting methodology. We finalized our proposal that the standard ASC ratesetting methodology for this comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to an office-based or radiology procedure is consistent for each HCPCS code regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced copayment liability for beneficiaries. Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: The wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, and the adjustment for devices furnished with full or partial credit or without cost. We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132), we did not make any changes to these policies. We are not proposing any changes to these policies.

D. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133) for a detailed discussion of the QualityNet security administrator requirements, including setting up a QualityNet account, and the associated timelines, for the CY 2014 payment determination and subsequent years. We are not proposing any changes to these policies.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 78 FR 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. We are not proposing any changes to these policies.

E. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. We are not proposing any changes to these policies.

2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135 through 75137) for a complete discussion of the minimum thresholds, minimum case volume, and data completeness for successful reporting for the CY 2014 payment determination and subsequent years. We are not proposing any changes to these policies.

3. Requirements for Data Submitted Via a CMS Online Data Submission Tool

a. Data Collection for ASC–6 and ASC–7

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74509) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75137 through 75138) for a complete discussion of the requirements for data collection and submission for the ASC–6: Safe Surgery Checklist Use and ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures measures for the CY 2015 payment determination and subsequent years. We are not proposing any changes to these policies.

b. Delayed Data Collection for ASC–9 and ASC–10

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75130), we adopted ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) and ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659), two additional chart-abstracted measures, and we finalized a policy that aggregate data (numerators, denominators, and exclusions) on all ASC patients would be collected via an online Web-based tool that would be made available to ASCs via the QualityNet Web site.

We finalized that the data collection time period would be the calendar year (January 1 to December 31) 2 years prior to the affected payment determination year, and the data collected would be submitted during the time period of January 1 to August 15 in the year prior to the affected payment determination year. Thus, for the CY 2016 payment determination, ASCs would be required to submit aggregate-level encounter data from January 1, 2014 to December 31, 2014 using our Web-based tool during the data submission window of January 1, 2015 to August 15, 2015 (78 FR 75138 through 75139).

On December 31, 2013, we issued guidance stating that we would delay the implementation of ASC–9 and ASC–10 for 3 months for the CY 2016 payment determination, with a resulting encounter period of April 1, 2014 to December 31, 2014 instead of January 1, 2014 to December 31, 2014 (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772879036*). The data

submission timeframe and the encounter period for subsequent years remain as previously finalized (78 FR 75139).

c. Delayed Data Collection and Proposed Exclusion for ASC–11 for the CY 2016 Payment Determination and Proposed Voluntary Data Collection for ASC–11 for CY 2017 and Subsequent Payment Determination Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period, where we adopted ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) beginning with the CY 2016 payment determination (78 FR 75129), and finalized the data collection and data submission timelines (78 FR 75138 to 75139). This measure assesses the rate of patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery based on completing both a pre-operative and post-operative visual function survey.

Since our adoption of this measure, we have come to believe that it may be operationally difficult at this time for ASCs to collect and report this measure. Specifically, we are concerned that the results of the survey used to assess the pre-operative and post-operative visual function of the patient may not be shared across clinicians and facilities, making it difficult for ASCs to have knowledge of the visual function of the patient before and after surgery. We are also concerned about the surveys used to assess visual function; the measure allows for the use of any validated survey and results may be inconsistent should clinicians use different surveys.

Therefore, on December 31, 2013, we issued guidance stating that we would delay data collection for ASC–11 for 3 months (data collection would commence with April 1, 2014 encounters) for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772879036*). We issued additional guidance on April 2, 2014, stating that we would further delay the implementation of ASC–11 for an additional 9 months, until January 1, 2015 for the CY 2016 payment determination, due to continued concerns (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228773811586*). Therefore, we are proposing to exclude ASC–11 Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) from the CY 2016 payment determination measure set. We would not subject ASCs to a payment reduction with respect to this measure for the CY 2016 payment determination.

We continue to believe that this measure addresses an area of care that is not adequately addressed in our current measure set and the measure serves to drive coordination of care (78 FR 75129). Further, we believe ASCs should be a partner in care with physicians and other clinicians using their facility and that this measure provides an opportunity to do so. Therefore, we are continuing to include this measure in the ASCQR Program measure set for the CY 2017 payment determination and subsequent years. However, we understand the concerns and, therefore, are proposing that data collection and submission be voluntary for this measure for the CY 2017 payment determination and subsequent years. ASCs would not be subject to a payment reduction for failing to report this measure during the period of voluntary reporting. For ASCs that choose to submit data, we continue to request that they submit such data using the means and timelines finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75138 to 75139). Data submitted voluntarily will be publicly reported as discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 75138 to 75139).

We invite public comment on this proposal.

4. Claims-Based Measure Data Requirements for the Proposed New Measure for the CY 2017 Payment Determination and Subsequent Years

We are proposing to adopt the ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, which is a claims-based measure that does not require any additional data submission apart from standard Medicare FFS claims. We are proposing that, for this measure, which uses ASC Medicare claims data as specified in the ASCQR Specifications Manual and does not require any additional data submission such as QDCs, we would use paid Medicare FFS claims from a 12-month period from July 1 of the year 3 years before the payment determination year to June 30 of the following year. Thus, for the CY 2017 payment determination for this measure, claims from July 1, 2014 to June 30, 2015 would be used. We note that we are proposing to adopt this measure under the Hospital OQR Program, as described in section XIII.H.2.c. of this proposed rule. This ASCQR Program time period provides for the timeliest data possible while aligning the proposed data submission requirements with our Hospital OQR Program proposal, which would use the claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years that we adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112).

We invite public comment on this proposal.

5. Data Submission Requirements for ASC–8 (Influenza Vaccination Coverage Among Healthcare Personnel) Reported via the National Healthcare Safety Network (NHSN) for the CY 2016 Payment Determination and Subsequent Years

a. Previously Adopted Requirements for the CY 2016 Payment Determination

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74510) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) for a complete discussion of the ASC–8 measure (Influenza Vaccination Coverage among Healthcare Personnel) (NQF #0431), including the data collection timeframe and the data reporting standard procedures for the CY 2016 payment determination.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140), we finalized our proposal to use the data submission and reporting standard procedures that have been set forth by the CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site for detailed procedures for enrollment (*http://www.cdc.gov/nhsn/ambulatory-surgery/enroll.html*), set-up (*http://www.cdc.gov/nhsn/ambulatory-surgery/setup.html*), and reporting (*https://sams.cdc.gov*) (user authorization through Secure Access Management Services (SAMS) is required for access to NHSN). We note that the reporting link has been updated in this proposed rule.

b. Proposed Data Collection Timeframes for the CY 2017 Payment Determination and Subsequent Years and Proposed Submission Deadlines for the CY 2016 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74510), we finalized that data collection for the CY 2016 payment determination would be

from October 1, 2014 through March 31, 2015 (the 2014–2015 influenza season data). We are proposing that for the CY 2017 payment determination and subsequent years, ASCs would collect data from October 1 of the year 2 years prior to the payment determination year to March 31 of the year prior to the payment determination year. For example, the CY 2017 payment determination would require data collection from October 1, 2015 to March 31, 2016.

In the CY 2014 OPPS/ASC proposed rule, we proposed that ASCs would have until August 15, 2015 to submit their 2014–2015 influenza season data (October 1, 2014 through March 31, 2015) to NHSN. We stated that this date is the latest date possible for data entry that would provide sufficient time for CMS to make the CY 2016 payment determinations and is aligned with the data entry deadline for the measures entered via the CMS online tool (78 FR 43670). While some commenters supported this proposal, others expressed disagreement with this proposal because it differed from the May 15 deadline proposed for the Hospital IQR Program (78 FR 27700, 50822) and the Hospital OQR Program (78 FR 43656, 75116 through 75117) and they believed this difference in deadlines could cause confusion, thereby disadvantaging ASCs (78 FR 75140). Other commenters believed that providing ASCs with a later deadline would provide an unfair advantage because ASCs would have longer to submit their data. Due to these concerns, we did not finalize the August 15, 2015 deadline. We stated that we intended to propose a submission deadline for this measure for the CY 2016 payment determination in this proposed rule.

In this proposed rule, we are proposing that May 15 of the year in which the influenza season ends be the submission deadline for each payment determination year, similar to the Hospital IQR and OQR Programs. For example, for the CY 2016 payment determination, ASCs would be required to submit their 2014–2015 influenza season data (October 1, 2014 through March 31, 2015) by May 15, 2015. Similarly, for the CY 2017 payment determination, ASCs would be required to submit their 2015–2016 influenza season data (October 1, 2015 through March 31, 2016) by May 15, 2016. We believe a May 15 reporting deadline would enable ASCs to use data summarizing the results of their previous influenza vaccination campaign to set targets and make plans for their influenza vaccination campaigns prior to the next influenza season. This deadline also would enable us to post and the public to review the summary data before the start of the next influenza season. Finally, this date aligns to the May 15 deadline used in the Hospital IQR and OQR Programs for this measure.

We invite public comment on this proposal.

6. ASCQR Program Validation of Claims-Based and CMS Web-Based Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641 through 53642) for a complete discussion of our policy not to require validation of claims-based measures (beyond the usual claims validation activities conducted by our administrative contractors) or Web-based measures for the ASCQR Program, which is in alignment with our requirements for the Hospital IQR and OQR Programs. We are not proposing any changes to this policy.

7. Extraordinary Circumstances Extensions or Exemptions for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75140 through 75141) for a complete discussion of our extraordinary circumstances extension or waiver process under the ASCQR Program. We are not proposing any substantive changes to these policies or the processes. However, in the future, we will refer to the process as the ''Extraordinary Circumstances Extensions or Exemptions'' process rather than the ''Extraordinary Circumstances Extensions or Waivers'' process.

We also are in the process of revising the Extraordinary Circumstances/Disaster Extension or Waiver Request form (CMS–10432), approved under OMB control number 0938–1171. We are updating the instructions and the form so that a hospital or facility may apply for an extension for all applicable quality reporting programs at the same time. In addition, the instructions for the form will be updated.

8. ASCQR Program Reconsideration Procedures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75141) for a complete discussion of our informal reconsideration process for the ASCQR Program for the CY 2014 payment determination and subsequent years. We are not proposing any changes to the informal reconsideration process.

XV. Proposed Changes to the Rural Provider and Hospital Ownership Exceptions to the Physician Self-Referral Law: Expansion Exception Process

A. Background

1. Statutory Basis

Section 1877 of the Act, also known as the ''physician self-referral law'' prohibits: (1) A physician from making referrals for certain designated health services payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) the entity from submitting claims to Medicare (or to another individual, entity, or third party payer) for those designated health services furnished as a result of a prohibited referral. The Act establishes a number of specific exceptions to the physician self-referral law and grants the Secretary the authority to create regulatory exceptions that pose no risk of program or patient abuse. Since the original enactment of the statute in 1989, we have published a series of final rules interpreting the statute and promulgating numerous exceptions.

Section 1877(d) of the Act sets forth exceptions related to ownership and investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership and investment interests in rural providers. Under the provision of section 1877(d)(2) of the Act, in order for an ownership or investment interest to qualify for the exception, the designated health services must be furnished in a rural area (as defined in section 1886(d)(2) of the Act), and substantially all of the designated health services furnished by the entity must be furnished to individuals residing in a rural area. Section 1877(d)(3) of the Act provides the hospital ownership exception, often referred to as the ''whole hospital exception,'' for ownership and investment interests in a hospital located outside of Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

2. Affordable Care Act Amendments to the Rural Provider and Hospital Ownership Exceptions to the Physician Self-Referral Law

Section 6001(a) of the Affordable Care Act amended the rural provider and whole hospital exceptions to the physician self-referral law to impose additional restrictions on physician ownership and investment in rural providers and hospitals. Section 6001(a) defines a ''physician owner or investor'' as a physician, or immediate family member of a physician, who has a direct or indirect ownership or investment interest in a hospital. We refer to hospitals with direct or indirect physician owners or investors as ''physician-owned hospitals.''

Section 6001(a)(3) of the Affordable Care Act established new section 1877(i) of the Act, which imposes additional requirements for physician-owned hospitals to qualify for the rural provider or whole hospital exception. In addition to other requirements, section 1877(i)(1) of the Act prohibits a physician-owned hospital from expanding its facility capacity beyond the number of operating rooms, procedure rooms, and beds for which the hospital was licensed as of March 23, 2010, unless an exception is granted by the Secretary.

Section 1877(i)(3) of the Act requires the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity. We refer to this process as the ''expansion exception process.'' Section 1877(i)(3)(A)(i) of the Act provides that a hospital qualifying as an ''applicable hospital'' or a ''high Medicaid facility'' may apply for an expansion exception. Section 1877(i)(3)(E) of the Act sets forth the eligibility criteria for applicable hospitals, which include criteria concerning inpatient Medicaid admissions, bed capacity, and bed occupancy. Section 1877(i)(3)(F) of the Act sets forth the eligibility criteria for high Medicaid facilities, which include a criterion concerning inpatient Medicaid admissions.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72240), we addressed many of the additional requirements that were established by section 6001(a) of the Affordable Care Act for the rural provider and whole hospital exceptions, including the prohibition on expansion of facility capacity. In that final rule with comment period, we finalized regulations at 42 CFR 411.362(b)(2) that prohibit a physician-owned hospital from increasing the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a physician-owned hospital that did not have a provider agreement in effect as of that date, but did have a provider agreement in effect on December 31, 2010, the effective date of such agreement), if the hospital seeks to avail itself of the rural provider or whole hospital exception.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74517), we promulgated regulations under 42 CFR 411.362(c) that govern the expansion exception process. Section 411.362(c)(2) sets forth the criteria for a physician-owned hospital to qualify for an expansion exception as an applicable hospital. Specifically, § 411.362(c)(2) states that: (1) The hospital's annual percent of total inpatient admissions under Medicaid must be equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located during the most recent fiscal year for which data are available as of the date that the hospital submits its exception request; (2) the hospital must be located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which data are available as of the date that the hospital submits its request; and (3) the hospital must have an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which data are available as of the date that the hospital submits its request.

Section 411.362(c)(3) specifies the criteria for a physician-owned hospital seeking an exception under the expansion exception process on the basis that it is a high Medicaid facility, including the requirement that, with respect to each of the 3 most recent fiscal years for which data are available as of the date that the hospital submits its exception request, the hospital must have an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42350 through 42352), we proposed that data from the CMS Healthcare Cost Report Information System (HCRIS) be used to determine whether a hospital satisfies the inpatient Medicaid admissions, bed capacity, and bed occupancy criteria for applicable hospitals and the inpatient Medicaid admissions criterion for high Medicaid facilities. We requested public comments concerning alternative data sources that could result in more accurate determinations as to whether a hospital satisfies the relevant criteria (76 FR 42350). The public comments that we received provided no persuasive support for a data source more accurate than the filed hospital cost report data reported to HCRIS and, therefore, we finalized the requirement to use filed hospital cost report data for purposes of facility capacity expansion exception requests in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74518). We refer to the filed hospital cost report data that are required under our existing regulations as ''HCRIS data'' in this proposal.

As required by section 1877(i)(3)(A) of the Act, the regulations addressing the expansion exception process in the CY 2012 OPPS/ASC final rule with comment period were issued by January 1, 2012, and the process was implemented on February 1, 2012.

B. Limitations Identified by Stakeholders Regarding the Required Use of HCRIS Data

Following the implementation of the expansion exception process, industry stakeholders informed us of what they believed to be certain limitations regarding the required use of HCRIS data, which we describe in the following two sections.

1. Medicaid Managed Care Data

Existing § 411.362(c)(2)(ii) provides that an applicable hospital must use filed cost report discharge data to estimate its annual percent of total inpatient admissions under Medicaid for the most recent fiscal year for which data are available. Existing § 411.362(c)(3)(ii) similarly provides that a high Medicaid facility must use filed cost report discharge data to estimate its annual percent of total inpatient admissions under Medicaid and such percent for every other hospital located in its county for each of the 3 most recent fiscal years for which data are available.

Since the issuance and implementation of this rule, several industry stakeholders have informed us that a correctly completed hospital cost report does not include Medicaid managed care admissions or discharges and, therefore, Medicaid managed care admissions and discharges are not available in HCRIS. The industry stakeholders claimed that, because HCRIS data does not include Medicaid managed care admissions or discharges, they are unable to satisfy §§ 411.362(c)(2)(ii) and (c)(3)(ii) and,

thus, cannot qualify for an exception under the existing expansion exception process, despite claiming to have served a significant number of total Medicaid patients.

After being notified of this issue, we confirmed that hospitals cannot report Medicaid managed care admissions or discharges through their hospital cost reports and that this information is not available in HCRIS. In addition, we have concluded that the information collected currently through HCRIS cannot be used to estimate Medicaid managed care admissions or discharges for purposes of estimating inpatient Medicaid admissions under §§ 411.362(c)(2)(ii) and (c)(3)(ii).

We believe that some physician-owned hospitals that serve a significant number of Medicaid managed care patients and are interested in the expansion exception process may fail to qualify for an exception based on the exclusion of Medicaid managed care data. Accordingly, as detailed in section XV.C. of this proposed rule, we are proposing to revise the expansion exception process to permit physician-owned hospitals to use filed hospital cost report data, data from internal data sources, or data from external data sources to estimate the required percentages of inpatient admissions under Medicaid. (We refer in this proposal to the non-HCRIS internal data sources and external data sources that we are proposing to permit for purposes of the expansion exception process as ''supplemental data sources.'') We believe that our proposal to permit the use of supplemental data sources is necessary to effectuate section 6001(a) of the Affordable Care Act for those physician-owned hospitals that are unable to satisfy the criteria for an expansion exception using only HCRIS data.

2. Hospitals That Lack Filed Cost Reports for the Relevant Fiscal Years

As stated above, existing § 411.362(c)(3)(ii) provides that a high Medicaid facility must use filed cost report discharge data to estimate its annual percent of total inpatient admissions under Medicaid and such percent for every other hospital located in its county for each of the 3 most recent fiscal years for which data are available. One industry stakeholder, seeking to avail itself of the whole hospital exception, stated that it would like to expand its facility capacity by qualifying as a high Medicaid facility. The stakeholder claimed that, although it treated Medicaid patients during the relevant 3-year period, it does not have filed cost report discharge data available for each of the relevant fiscal years because it was not a Medicare participating provider during the entire period. The industry stakeholder further claimed that it is unable to request an exception as a high Medicaid facility until it has 3 years of the required filed cost report data.

The stakeholder is correct that a hospital that has not participated as a provider in the Medicare program for all of the 3 most recent fiscal years for which data are available would be precluded from seeking a facility expansion exception. It would be similarly prohibitive if the hospitals in the county in which the requesting hospital is located were not Medicare participating providers or were not participating in the Medicare program for the entire period for which comparisons are required under the statute and our regulations. We find this to be another persuasive reason to permit the use of supplemental data sources and, as such, we are proposing to permit the use of other data sources, as further detailed in section XV.C. of this proposed rule, for physician-owned hospitals to estimate the percentages of inpatient admissions under Medicaid for § 411.362(c)(3)(ii). We believe that our proposal will enable physician-owned hospitals to perform the comparison set forth in § 411.362(c)(3)(ii), even if the requesting hospital and/or another hospital located in its county lacks filed hospital cost report data for some or all of the relevant fiscal years. We note that the proposal would apply regardless of the reason that the requesting hospital and/or another hospital in its county lacks filed hospital cost report data.

The industry stakeholder that informed us of this issue would like to qualify as a high Medicaid facility; therefore, the stakeholder's comments addressed only the inpatient Medicaid admissions criterion for high Medicaid facilities. However, as stated above, hospitals seeking to qualify as an applicable hospital also use filed hospital cost report data for the inpatient Medicaid admissions, bed capacity, and bed occupancy criteria set forth in § 411.362(c)(2). We recognize that these hospitals may also lack filed hospital cost report data or may be subject to comparisons against other hospitals that lack filed cost report data for the relevant fiscal year. Therefore, as further detailed in section XV.C. of this proposed rule, we are proposing to permit the use of supplemental data sources for the inpatient Medicaid admissions, bed capacity, and bed occupancy criteria for applicable hospitals.

C. Proposed Changes To Permit Supplemental Data Sources in the Expansion Exception Process

Given the limitations regarding the required use of HCRIS data described in sections XV.B.1. and XV.B.2. of this proposed rule, we are proposing to revise our regulations at §§ 411.362(c)(2)(ii), (c)(2)(iv), (c)(2)(v), and (c)(3)(ii) to permit physician-owned hospitals to use data from certain internal data sources or external data sources, in addition to HCRIS data, in order to estimate the percentages of inpatient Medicaid admissions, and to determine the bed capacities and the bed occupancy rates referenced in those sections. We are not prescribing that hospitals use a specific individual data source or combination of data sources.

We are proposing that, for purposes of the expansion exception process, internal data sources are sources generated, maintained, or under the control of the Department. The following list provides examples of internal data sources that we are proposing physician-owned hospitals may use in the expansion exception process:

- Healthcare Cost and Utilization Project (HCUP)—HCUP is a family of health care databases and related software tools and products developed through a Federal-State-industry partnership and sponsored by the Agency for Healthcare Research and Quality (AHRQ). HCUP databases bring together the data collection efforts of State data organizations, hospital associations, private data organizations, and the Federal government to create a national information resource of encounter-level health care data (*HCUP Partners*).
- Medicaid Statistical Information System (MSIS)—States report Medicaid data through MSIS. Through this system, States submit raw eligibility and claims data to CMS, which CMS uses to produce Medicaid program characteristics and utilization information.
- Medicaid Analytic Extract (MAX)—MAX data are person-level data files on Medicaid eligibility, service utilization, and payment information for all individuals, whether or not they used any Medicaid services in a given calendar year. The purpose of MAX is to produce data to support research and policy analysis on Medicaid populations.

We also are seeking public comments that recommend other possible internal data sources.

We are proposing that, for purposes of the expansion exception process,

external data sources are data sources generated, maintained, or under the control of a State Medicaid agency. We are seeking public comments that recommend other possible external data sources, including those of other State agencies or departments.

We are proposing to define the terms ''internal data source'' and ''external data source'' in § 411.351. We recognize the need for an accurate and consistent expansion exception process. Accordingly, we are proposing to define ''internal data source'' to include only non-HCRIS data sources that are reliable and transparent, and that maintain or generate data that are accurate, complete, and objectively verifiable for purposes of the expansion exception process. In addition, we are proposing to define ''external data source'' to include only data sources that are reliable and transparent, and that maintain or generate data that are accurate, complete, and objectively verifiable for purposes of the expansion exception process. Finally, we are proposing in § 411.351 that internal data sources and external data sources must maintain data that are readily available and accessible to the requesting hospital, comparison hospitals, and to CMS for purposes of the expansion exception process. We note that the expansion exception process includes both the physician-owned hospital's completion of its request and CMS' consideration of the physician-owned hospital's request.

We believe that the supplemental data sources should—

- Be transparent regarding what comprises the data, where the data originated, and the manner and method by which the data source received the data;
- Be maintained on a secure database that prevents distortion or corruption of data and that ensures the accuracy of the data;
- Contain sufficient information to enable accurate estimates of the percentages of inpatient Medicaid admissions, and accurate determinations of bed capacities and bed occupancy rates;
- Contain sufficient information to enable the comparisons required by §§ 411.362(c)(2)(ii), (c)(2)(iv), (c)(2)(v), and (c)(3)(ii) for the fiscal year(s) at issue; and
- Contain sufficiently clear and detailed data that will enable multiple users to produce consistent results and outcomes when using the same data set.

Under the existing expansion exception process, CMS uses HCRIS data to provide the average percent of total inpatient Medicaid admissions per county, the average bed capacity per State, the national average bed capacity, and the average bed occupancy rate per State on the CMS Web site at: *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html*. If we finalize our proposal to permit the use of supplemental data sources, we plan to continue to provide HCRIS-based information and issue guidance on the potential use of supplemental data sources on the CMS Web site.

We recognize that if a physician-owned hospital uses data from a supplemental data source, the hospitals may ultimately need to make estimates or determinations in addition to those referenced in our existing regulations. Accordingly, we are proposing to revise our regulations to allow for the additional estimates or determinations that may be necessary under our revised process. Specifically, we are proposing to permit a requesting hospital to use data from a supplemental data source to:

- Estimate its own annual percentage of inpatient Medicaid admissions (§ 411.362(c)(2)(ii)).
- Estimate the average percentage with respect to such admissions for all hospitals located in the county in which the hospital is located (§ 411.362(c)(2)(ii)).
- Determine the average bed capacity in the State in which the hospital is located (§ 411.362(c)(2)(iv)).
- Determine the national average bed capacity (§ 411.362(c)(2)(iv)).
- Determine its own average bed occupancy rate (§ 411.362(c)(2)(v)).
- Determine the average bed occupancy rate for the State in which the hospital is located (§ 411.362(c)(2)(v)).
- Estimate its annual percentage of total inpatient admissions under Medicaid for each of the 3 most recent fiscal years for which data are available (§ 411.362(c)(3)(ii)).
- Estimate the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located for each of the 3 most recent fiscal years for which data are available (§ 411.362(c)(3)(ii)).

We note that section 1877(i)(3)(F) of the Act requires that a high Medicaid facility use data from the 3 most recent fiscal years for which data are available. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74518), we stated that we consider the most recent fiscal year for which data are available to be the most recent year for which HCRIS contains data from at least 6,100 hospitals. We currently apply this standard to expansion exception requests for both applicable hospitals and high Medicaid facilities. We are proposing to revise our standard so that the most recent fiscal year for which data are available would be the year for which the data source(s) used in an expansion exception request contain sufficient data to perform the comparisons required under §§ 411.362(c)(2)(ii), (c)(2)(iv), (c)(2)(v), and (c)(3)(ii). Specifically, we are proposing that data sources, either alone or in combination with other data sources, would be considered to contain ''sufficient data'' if they contain all data from the requesting hospital and each hospital to which the requesting hospital must compare itself that are necessary to perform the estimates required in the expansion exception process. In addition, with respect to a hospital seeking an expansion exception as an applicable hospital, we are proposing that, in order to be considered to contain ''sufficient data,'' the data sources, either alone or in combination with other data sources, must contain the data necessary to determine the State and national average bed capacity and the average bed occupancy rate in the State in which the requesting hospital is located for purposes of the expansion exception process.

Modifying our current interpretation of ''the most recent fiscal year for which data are available'' would allow physician-owned hospitals in counties or States where all data necessary to perform the required estimates and determinations have been filed or otherwise included in the permissible data source(s) to proceed with an expansion exception request, even if hospitals unrelated to the request have not filed or otherwise submitted data to the source(s) being used in the hospital's request. We also are proposing to require that data from the same fiscal year be used for the applicable hospital eligibility criteria at §§ 411.362(c)(2)(ii), (c)(2)(iv), (c)(2)(v), even if the hospital uses multiple data sources for those criteria. We believe that requiring the use of data from the same fiscal year will ensure consistency and equitability in the expansion exception process. We are seeking public comments on our proposal to revise the standard that determines the most recent fiscal year(s) for which data are available, as well as other ways to define ''sufficient data'' for purposes of the expansion exception process.

In addition, we are proposing to require that the requesting hospital provide actual notification directly to hospitals whose data are part of the comparisons set forth under

§§ 411.362(c)(2)(ii) and (c)(3)(ii) of the regulations. Under proposed § 411.362(c)(5), the notification must be in writing, in either electronic or hard copy form, and must be provided at the same time that the hospital discloses on any public Web site for the hospital that it is requesting an exception. This additional safeguard would ensure that comparison hospitals are aware of the opportunity to confirm or dispute the accuracy or reliability of the data in the physician-owned hospital's request.

Finally, our existing regulations at § 411.362(c)(5) set forth the process for community input and the timing of a complete expansion exception request. These regulations provide for a 30-day comment period following publication in the **Federal Register** of notice of the physician-owned hospital's expansion exception request and a 30-day rebuttal period for the requesting hospital to respond, if it chooses, to any written comments that CMS receives from the community. Currently, an expansion exception request is considered complete at the end of the 30-day comment period if CMS does not receive written comments from the community. If CMS receives written comments from the community, the request is considered complete at the end of the 30-day rebuttal period, regardless of whether the requesting hospital submits a rebuttal statement. We believe that permitting the use of data from an internal data source or an external data source would likely require additional time for our review of an expansion exception request, including any comments submitted with respect to the request. For example, CMS may need to obtain the data from the original source, confirm that the data presented in the request are an accurate representation of the original source data, and objectively verify the estimates and determinations presented in the request. Therefore, we are proposing to revise our regulations at § 411.362(c)(5) to extend the date by which certain expansion exception requests will be deemed complete. Specifically, we are proposing to revise § 411.362(c)(5) to provide that, where the request, any written comments, and any rebuttal statement include only HCRIS data, an expansion exception request will be deemed complete no later than: (1) The end of the 30-day comment period if no written comments from the community are received; and (2) the end of the 30-day rebuttal period if written comments from the community are received, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement. We also are proposing that, where the request, any written comments, or a rebuttal statement includes data from a supplemental data source, an expansion exception request will be deemed complete no later than: (1) 180 days after the end of the 30-day comment period if no written comments from the community are received; and (2) 180 days after the end of the 30-day rebuttal period if written comments from the community are received, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement.

We note that additional revisions may be necessary to conform our regulations at § 411.362(c) if we finalize our proposal to permit the use of supplemental data sources.

D. Additional Considerations

As stated above, we recognize the need for an accurate and consistent expansion exception process. We are aware that data sources have unique characteristics due to their inputs, collection methods, compilation, and other factors, and will take this into consideration if we finalize our proposal to permit the use of supplemental data sources. In an effort to implement an accurate and consistent expansion exception process, we are seeking public comments on the utility, appropriateness, and limitations of our proposal to permit the use of supplemental data sources. Specifically, we are seeking public comments that:

- Address whether permitting the use of supplemental internal or external data sources would significantly affect the outcomes for any of the estimates or determinations required in our regulations.
- Address whether permitting the use of supplemental data sources would materially affect a physician-owned hospital's ability to request an exception or CMS' determination on an exception request.
- Describe the length of time that would be necessary to obtain or generate the required data from a specific data source.
- Address whether and when the data will be available and accessible per fiscal year.
- Address whether the data will be available and accessible in a format that enables the requesting hospital to perform the necessary comparisons.
- Describe how supplemental data sources could or should be prioritized, including, but not limited to, rankings related to accuracy or reliability.
- Describe how data from a particular data source could be used in the expansion exception process. We encourage commenters to specify whether a particular data source already maintains the percentages or rates required, or whether calculations will be necessary to generate the required percentages or rates. If calculations will be necessary, we are requesting that commenters describe the calculations.
- Describe the cost to industry stakeholders, State governments, and the Federal government for obtaining or generating data from any potential data sources. We consider cost to include both resources (for example, human capital and information technology) and actual financial burden (for example, fees to use or purchase the data). We also seek public comments on whether any additional burdens would affect the quality of care for beneficiaries as a result of additional costs borne by a requesting hospital.

XVI. Proposed Revision of the Requirements for Physician Certification of Hospital Inpatient Services Other Than Psychiatric Inpatient Services

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27644 through 27650), we discussed the statutory requirement for certification of hospital inpatient services for payment under Medicare Part A. The certification requirement for inpatient services other than psychiatric inpatient services is found in section 1814(a)(3) of the Act, which provides that Medicare Part A payment will only be made for such services ''which are furnished over a period of time, [if] a physician certifies that such services are required to be given on an inpatient basis.''

In commenting on our FY 2014 proposal, some commenters argued that the statutory reference to services furnished ''over a period of time'' and the then-existing regulation's lack of any specific deadline for physician certifications in nonoutlier cases indicate that no certification is required for short-stay cases. In support of their argument, the commenters cited the legislative history of section 1814(a)(3) of the Act, which these commenters interpreted as indicating that the certification requirements should apply only to certain long-term stays.

As we indicated in our response to these public comments in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50939), we do not agree with the assertion that the only possible interpretation of the statute is that the requirement for physician certification only applies to long-stay cases. The statute does not define ''over a period of time,'' and further provides that ''such

certification shall be furnished only in such cases, and with such frequency, and accompanied by such supporting material . . . as may be provided by regulations.'' By this language, Congress explicitly delegated authority to the agency to elucidate this provision of the statute by regulation.

In our current regulations, we have interpreted the statute's requirement of a physician certification for inpatient hospital services furnished ''over a period of time'' to apply to all inpatient admissions. While this is not the only possible interpretation of the statute, we believe that it is a permissible interpretation.

We continue to believe that the requirement of an order from a physician or other qualified practitioner in order to trigger an inpatient hospital admission as specified in 42 CFR 412.3 is necessary for all inpatient admissions. As described more fully in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50938 through 50954), the requirement for a physician order for a hospital inpatient admission has long been clear in the Medicare hospital conditions of participation (CoPs), and we promulgated § 412.3 to make more explicit that admission pursuant to this order is the means whereby a beneficiary becomes a hospital inpatient and, therefore, is required for payment of hospital inpatient services under Medicare Part A. A beneficiary becomes a hospital inpatient when admitted as such after a physician (or other qualified practitioner as provided in the regulations) orders inpatient admission in accordance with the CoPs, and Medicare pays under Part A for such an admission if the order is documented in the medical record. The order must be supported by objective medical information for purposes of the Part A payment determinations. Thus, the physician order must be present in the medical record and be supported by the physician admission and progress notes in order for the hospital to be paid for hospital inpatient services.

As further noted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50938 through 50954), we believe the additional certification requirements now specified under 42 CFR 424.13(a)(2), (a)(3), and (a)(4) (that is, the reason for hospitalization, the estimated time the patient will need to remain in the hospital, and the plan of posthospital care, if applicable) generally can be satisfied by elements routinely found in a patient's medical record, such as progress notes.

However, as we look to achieve our policy goals with the minimum administrative requirements necessary, and after considering previous public comments and our experience with our existing regulations, we believe that, in the majority of cases, the additional benefits (for example, as a program safeguard) of formally requiring a physician certification may not outweigh the associated administrative requirements placed on hospitals. Therefore, while we continue to believe that the inpatient admission order is necessary for all inpatient admissions, we are proposing to require such orders as a condition of payment based upon our general rulemaking authority under section 1871 of the Act rather than as an element of the physician certification under section 1814(a)(3) of the Act. Section 1871 of the Act authorizes the Secretary ''to prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [Title XVIII].'' A clear regulatory definition of when and how a beneficiary becomes an inpatient is necessary to carry out the administration of Medicare Part A. Section 1861(b) of the Act defines ''inpatient hospital services'' as certain items and services furnished to ''an inpatient of a hospital,'' but does not define ''an inpatient of a hospital.'' Accordingly, 42 CFR 412.3 provides the necessary definition for purposes of Medicare Part A payment by clarifying when ''an individual is considered an inpatient of a hospital, including a critical access hospital.'' We are proposing to remove paragraph (c) from § 412.3. As we are proposing to rely on a different statutory authority for such regulation, an admission order would no longer be a required component of physician certification of medical necessity.

As to the physician certification requirement, we maintain that our existing longstanding policy is based upon a permissible interpretation of section 1814(a)(3) of the Act pursuant to that provision's express delegation of authority to the agency to determine the circumstances under which such certification should be required. Nonetheless, after consideration of public feedback, our experience under the existing regulations, and our policy goals, we are proposing to change our interpretation of section 1814(a)(3) of the Act to require a physician certification only for long-stay cases and outlier cases.

As noted above, we believe that, in most cases, the admission order, medical record, and progress notes will contain sufficient information to support the medical necessity of an inpatient admission without a separate requirement of an additional, formal, physician certification. However, we believe that evidence of additional review and documentation by a treating physician beyond the admission order is necessary to substantiate the continued medical necessity of long or costly inpatient stays. While granting the Secretary broad discretion to determine the circumstances under which a physician certification should be required, the statute specifies that the certification by a physician with respect to inpatient hospital services (other than inpatient psychiatric hospital services) ''shall be furnished no later than the 20th day'' of the stay. Because the statute specifically requires that certification must occur no later than the 20th day, we believe that, at a minimum, Congress intended that physicians should conduct a more thorough review of such cases to help ensure that all requirements of medical necessity continue to be met. We also note the current regulations at § 424.13(f)(2) specify our longstanding requirement that the physician certification for cost outlier cases occur no later than 20 days into the hospital stay, and we are not proposing to change the requirements for these cases. Therefore, we believe that, for nonoutlier cases, 20 days is also an appropriate minimum threshold for the physician certification, and we are proposing to define long-stay cases as cases with stays of 20 days or longer.

Specifically, in this proposed rule, we are proposing to revise paragraph (a) of § 424.13 to specify that ''Medicare Part A pays for inpatient hospital services (other than inpatient psychiatric facility services) for cases that are 20 inpatient days or more, or are outlier cases under subpart F of Part 412 of this chapter, only if a physician certifies or recertifies the following:

(1) The reasons for either—

(i) Continued hospitalization of the patient for medical treatment or medically required diagnostic study; or

(ii) Special or unusual services for cost outlier cases (under the prospective payment system set forth in subpart F of part 412 of this chapter).

(2) The estimated time the patient will need to remain in the hospital.

(3) The plans for posthospital care, if appropriate.''

We also are proposing to revise paragraph (b) of § 424.13 to specify that certifications for long-stay cases must be furnished no later than 20 days into the hospital stay.

Because the care furnished in inpatient psychiatric facilities is often purely custodial and therefore not covered under Medicare and because the primary purpose of the certification

of these cases is to help ensure that Medicare pays only for services of the type appropriate for Medicare coverage, we are not proposing changes to the certification requirements for inpatient psychiatric hospital services.

As discussed more fully in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50942 through 50943), there also are inherent differences in the operation of and beneficiary admission to IRFs. Therefore, we also are not proposing any changes to the admission requirements for IRFs.

We are inviting public comment on these proposals.

XVII. CMS-Identified Overpayments Associated With Payment Data Submitted by Medicare Advantage (MA) Organizations and Medicare Part D Sponsors (Proposed §§ 422.330 and 423.352)

A. Background

Medicare Part C and Part D payments to Medicare Advantage (MA) organizations and Part D sponsors are determined, in part, using data submitted to CMS by the MA organizations and Part D sponsors. These ''payment data'' include diagnosis data that are used by CMS to risk adjust Part C and Part D payments, Prescription Dug Event (PDE) data that are used by CMS to cost reconcile various Part D subsidies, as well as other types of data discussed below. Through our review and oversight of payment data submitted by MA organizations and Part D sponsors, CMS identifies situations where MA organizations and/or Part D sponsors have submitted payment data to CMS that should not have been submitted—either because the data submitted are inaccurate or because the data are inconsistent with Part C and Part D requirements. (Throughout this section, we refer to these data submissions as ''erroneous payment data.'') If an MA organization or Part D sponsor submits erroneous payment data to CMS, the MA organization or Part D sponsor can address errors by submitting corrected data to the CMS payment systems, and our approach thus far to these kinds of situations has been to request that MA organizations and Part D sponsors make these kinds of data corrections voluntarily.

However, in instances in which the MA organization or Part D sponsor fails to make the requested data correction, the payment amount calculated for the plan may also be incorrect. As a result, we have concluded that CMS needs to establish a formal process that allows us to recoup overpayments that result from the submission of erroneous payment data by an MA organization or Part D sponsor in the limited circumstances when the organization fails to correct those data. We emphasize that, in our experience, the circumstance where an MA organization or Part D sponsor fails to correct identified erroneous payment data arises very infrequently.

This proposed new process is not intended to replace established recovery and appeals processes such as the Risk Adjustment Data Validation (RADV) audit dispute and appeal process described at 42 CFR 422.311 or the Part D payment appeals process described at 42 CFR 423.350. This proposed process would not constitute a change to the existing Part C or Part D payment methodologies. Rather, we are merely proposing to adopt a procedural mechanism for recouping overpayments that CMS will use in those limited circumstances when an MA organization or Part D sponsor fails to correct erroneous payment data. The established recovery and appeals processes do not support this scenario. Section 1856(b) of the Act establishes authority for us to add standards for Part C and MA organizations. Section 1853 of the Act for Part C and sections 1860D–14 and 1860D–15 of the Act for Part D establish the methodology for computing payments to MA organizations and Part D sponsors, respectively. We believe that inherent in the methodology under which payments to MA organizations and Part D sponsors are calculated is the authority for CMS to establish a process for identifying and recouping overpayments, in order to ensure that payments are made consistent with the payment framework established in the statute. Therefore, we are proposing to implement such a process through changes to our regulations.

1. Medicare Part C Payment Background

For Medicare Part C, CMS makes prospective monthly payments to MA organizations for each enrollee in the plan. CMS' monthly Part C payment for each MA plan enrollee consists of two components: The capitated payment for each enrollee (calculated as the plan-specific county payment rate multiplied by the enrollee risk score), plus the plan rebate amount (if any). The plan-specific county rates and the plan rebate amount are based on the bid approved by CMS and are set in advance for a payment year. In addition, payment rates may be adjusted for enrollees with end-stage renal disease, enrollees in Medical Savings Account MA plans, and enrollees in religious fraternal benefit society MA plans under § 422.304. Prospective payments are made during the year, subject to a reconciliation after the end of the year.

CMS adjusts the plan-specific county payment rate for each enrollee based on an enrollee risk score. Enrollee risk scores are determined using the CMS-Hierarchical Condition Category (CMS–HCC) risk adjustment model in effect for the payment year, plan-submitted diagnoses for the data collection year, and other data that CMS determines to be appropriate to perform risk adjustment. The CMS–HCC model is prospective in that it uses diagnosis information from a base year (data collection year) to adjust payments for the next year (payment year or coverage year). For example, the risk adjustment model uses diagnosis data from 2013 to adjust payments to MA organizations for coverage in 2014.

To determine the appropriate risk score for each beneficiary, CMS uses demographic characteristics of beneficiaries and diagnostic information gathered in the administration of Original Medicare and submitted by MA organizations. MA organizations are required to submit an occurrence of an HCC model-relevant diagnosis only once during the data collection year, even though a beneficiary may have several service dates in a data collection year associated with a given diagnosis. The minimum data elements currently collected from MA organizations under § 422.310 are: Health Insurance Claim (HIC) Number; provider type (hospital inpatient, hospital outpatient, or physician); service from date; service through date; and ICD–9 codes at the level of specificity used by the HCC model. In addition, effective January 2012, CMS collects more detailed Part C utilization and cost data from MA organizations (often referred to as encounter data), that are used in setting the risk score.

CMS allows 13 months after the end of a data collection year for MA organizations to update the risk adjustment data submitted under § 422.310; this period provides MA organizations an opportunity to identify and correct errors in data they have submitted for that data collection year (that is, by deleting diagnoses from CMS' systems) and to identify and submit additional diagnoses not submitted during the data collection year. During this 13-month period, CMS uses the diagnosis data that MA organizations have submitted up to that point to calculate interim beneficiary risk scores for adjusting prospective payments made during the payment year. The end of this 13-month period is called the final risk adjustment data

submission deadline (§ 422.310(g)(2)(ii)).

For each payment year, we apply three sets of risk scores to adjust payments: Initial and midyear risk scores during the payment year (both sets are based on incomplete diagnosis data from the data collection year), and final risk scores after the payment year using data MA organizations submitted as of the final deadline for risk adjustment data (which reflect complete data for the data collection year). During the year, CMS makes monthly prospective payments to the MA organization based on enrollment information and using interim risk scores calculated based on the data available before the final risk adjustment data submission deadline. CMS calculates the preliminary risk scores before the first payment is made (that is, for January of the payment year) and again in the middle of the payment year; an interim reconciliation is made so that the prospective payments to MA organizations are based on the most recent risk score available for each enrollee.

After the final risk adjustment data submission deadline, CMS conducts a reconciliation, in which the prospective Part C payments made during the coverage year based on interim risk scores are compared to Part C payments recalculated using final risk scores and the latest enrollment data. While changes in enrollment data are updated every month by CMS' systems during the payment year (for example, disenrollments from MA organizations and dates of death from the Social Security Administration (SSA)), risk adjustment data are not finalized until the final risk adjustment data submission deadline.

We note that after the final risk adjustment data submission deadline, MA organizations are allowed to submit corrected diagnosis data to correct overpayments they received from CMS. However, after this deadline, MA organizations are not allowed to submit diagnosis codes for additional payment, as specified in § 422.310(g)(2)(ii); this provision was recently adopted in the final rule entitled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29843). When such corrections are submitted, CMS conducts another reconciliation to correct the payments made to the MA organization using the established payment adjustment process. In addition, under § 422.311, CMS conducts RADV audits of the risk adjustment data submitted by MA organizations pursuant to § 422.310. Such RADV audits are conducted at the MA organization contract level and are designed to calculate a contract–level error rate and payment adjustment amount for a specific payment year under audit.

2. Medicare Part D Payment Background

For Medicare Part D, the Medicare Prescription Drug Benefit, Improvement, and Modernization Act (MMA), which amended the Act by adding Part D under Title 18, provides four payment mechanisms: Direct subsidy (codified at § 423.329(a)); reinsurance subsidy (codified at § 423.329(c)); low income subsidy (codified at §§ 423.780 and 423.782); and risk sharing (codified at § 423.336(b)). As a condition of payment, section 1860D–15(d)(2)(A) of the Act requires that Part D sponsors submit data and information necessary for CMS to carry out those payment provisions. Part D sponsors submit PDE data, direct and indirect remuneration (DIR) data, and risk adjustment data to CMS for payment purposes.

Throughout the coverage year, CMS makes prospective payments to Part D sponsors that cover three subsidies: The direct subsidy; the low income cost-sharing subsidy; and the reinsurance subsidy. The payment amounts are based on information in the approved basic bid and on data received by CMS that are used to update payments throughout the year. Following the end of the coverage year, the prospective payments are reconciled against the actual costs of the Part D sponsor. Reconciliation of the low income cost-sharing subsidy and reinsurance and the calculation of risk sharing are based on PDE and DIR data submitted by the Part D sponsor, as well as data captured from other CMS systems. CMS instructs Part D sponsors that they should continually monitor their submitted data throughout the year in order to ensure that the reconciliation and final payment determinations are accurate.

The final payment determination may be reopened and revised at CMS discretion under § 423.346. In our final rule, ''Medicare Program; Medicare Prescription Drug Benefit'' published in the **Federal Register** on January 28, 2005 (70 FR 4194), we stated that including the Medicare Part D reopening provision at § 423.346 would ''ensure that the discovery of any overpayment or underpayments could be rectified'' (70 FR 4316). However, this is only possible to the extent that the data submitted by Part D sponsors are accurate. Accordingly, prior to making a payment determination for a coverage year, either through a reconciliation described at § 423.343 or a reopening described at § 423.346, CMS periodically makes requests that Part D sponsors correct payment data that do not comply with program requirements (that is, what we have defined as ''erroneous payment data''). These may be general requests to all Part D sponsors to look for a type of payment issue (for example, the Health Plan Management System (HPMS) memorandum, ''Correcting Missing, Invalid, and Inactive Prescriber Identifiers on 2012 Prescription Drug Event (PDE) Records,'' dated February 4, 2013) or targeted requests to specific Part D sponsors known to have particular payment issues (as was done in the ''Prescriber NPI Project'' announced in the HPMS memorandum, ''Announcement of Prescriber NPI Project and Web site Release,'' dated December 4, 2012). If a Part D sponsor fails to correct its payment data, the erroneous payment data remain in the payment system, rendering the reopening provision ineffective for rectifying overpayments as it was intended.

B. Provisions of our Proposals

In this proposed rule, we are proposing to establish regulations at 42 CFR 422.330, relating to MA organizations, and at 42 CFR 423.352, relating to Part D sponsors, that would specify the procedural mechanism used by CMS to recoup overpayments associated with errors identified by CMS in payment data submitted by MA organizations and Part D sponsors. We also are proposing to create a process whereby an MA organization or Part D sponsor can appeal the finding that payment data are erroneous.

We note that our proposal is intended to establish a process to address errors and payment adjustments that are not addressed by existing processes such as the RADV audit and appeal process or overpayments identified by the MA organization or Part D sponsor, which are subject to separate procedures. If an MA organization or a Part D sponsor self-identifies an overpayment, that overpayment must be reported and returned to CMS in accordance with section 1128J(d) of the Act, which was added by section 6402 of the Affordable Care Act. Regulations implementing section 1128J(d) have recently been adopted at §§ 422.326 and 423.360 in the final rule entitled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29843).

1. Proposed Definitions of ''Payment Data'' and ''Applicable Reconciliation Date''

We are proposing to define ''payment data'' to mean data controlled and submitted to CMS by an MA organization or a Part D sponsor that is used for payment purposes (proposed §§ 422.330(a) and 423.352(a)). The MA organization or Part D sponsor is responsible for the accuracy of such data. MA organizations and Part D sponsors are currently required to attest to the accuracy, completeness, and truthfulness of such data under § 422.504(l) and § 423.505(k), respectively. For Medicare Part C, the data submitted by the MA organization to CMS include, for example, enrollment data and risk adjustment data specified at § 422.310. For Medicare Part D, data submitted by the Part D sponsor to CMS include enrollment data and data submitted under § 423.329(b)(3) (risk adjustment data), § 423.336(c)(1) (cost data), § 423.343 (data for retroactive adjustments and reconciliations), and data provided for purposes of supporting allowable reinsurance costs and allowable risk corridor costs as defined in § 423.308, which include data submitted to CMS regarding direct or indirect remuneration (DIR).

There are additional payment-related data that CMS uses to calculate Part C and Part D payments that are submitted directly to CMS by other entities, such as the Social Security Administration (SSA). These entities are the authoritative source for data that they submit to CMS, and MA organizations and Part D sponsors are not the official source for data submitted by these other entities. For example, the SSA is the authoritative source for date of death of Medicare beneficiaries. An MA organization or a Part D sponsor generally does not submit a beneficiary's date of death directly to CMS' systems; such data come from the SSA data feed. When the SSA submits corrected data regarding a beneficiary's date of death to CMS, CMS' systems recalculate the payments made to the plan for that beneficiary and correct any incorrect payment through a routine retroactive payment adjustment process. Therefore, the proposed definition of ''payment data'' refers only to data that the MA organization or Part D sponsor controls and submits to CMS for payment purposes.

For MA organizations under Part C, we are proposing that the ''applicable reconciliation date'' occurs on the date of the annual final risk adjustment data submission deadline set under § 422.310(g)(2)(ii). While changes in enrollment data are updated every month by CMS' systems during the payment year (for example, disenrollments from MA organizations and dates of death from the SSA), risk adjustment data are not finalized until the final risk adjustment data submission deadline. Prior to that deadline, CMS allows the MA organization to continue submitting corrected and new diagnosis data. However, once the final risk adjustment data submission deadline has passed, CMS uses this final diagnosis data to calculate the final risk scores for the payment year. CMS then uses those final risk scores for payment reconciliation. By proposing that the applicable reconciliation date occurs on the risk adjustment data submission deadline, we intend to signal that the normal payment process for the year has been concluded.

For Part D sponsors, we are proposing that the ''applicable reconciliation date'' is the later of either: The annual deadline for submitting PDE data for the annual Part D payment reconciliations referenced in § 423.343(c) and (d); or the annual deadline for submitting DIR data. The annual deadline for submitting PDE data is the last Federal business day prior to June 30 of the year following the coverage year being reconciled. The annual deadline for submitting DIR data is announced annually through subregulatory guidance and generally occurs around the last business day in June of the year following the coverage year being reconciled. We selected these events to define the Part D applicable reconciliation date because data must be submitted by these deadlines in order to be used for the purposes of the final Part D payment reconciliation.

We note that the proposed definitions of ''applicable reconciliation date'' are nearly identical to the definitions of ''applicable reconciliation'' at existing §§ 422.326 and 423.360. Similarly, the proposed definitions of ''payment data'' are nearly identical to the definitions of ''funds'' at existing §§ 422.326 and 423.360. Although proposed §§ 422.330 and 423.352 address overpayments to MA organizations and Part D sponsors that have been identified by CMS, whereas §§ 422.326 and 423.360 address overpayments that are identified by the MA organization or Part D sponsor, we do not believe that the issue of which entity (CMS or the plan) identified the overpayment is relevant to the question of when the overpayment occurred or what information is at issue. Both the current policy regarding overpayments identified by MA organizations and Part D sponsors and the proposed policy regarding CMS-identified overpayments are intended to address circumstances in which an overpayment has been identified; therefore, we believe it would be appropriate and avoid unnecessary confusion to use similar definitions.

2. Request for Corrections of Payment Data

We are proposing that if CMS identifies an error in payment data submitted by an MA organization or Part D sponsor that would result in an overpayment, CMS may request that the organization make corrections to the applicable payment data (proposed §§ 422.330(b) and 423.352(b)). We are proposing that CMS would make the request through a data correction notice that would contain or make reference to the specific payment data identified by CMS as erroneous, the reason why CMS believes that the payment data are erroneous, and the timeframe in which the MA organization or Part D sponsor must make corrections to the data. CMS may identify payment data that need to be corrected through a variety of different mechanisms, including, but not limited to, CMS analyses of payment data, CMS audits, or communications with the MA organization or Part D sponsor.

We understand that, at some point, it would no longer be practical for MA organizations and Part D sponsors to correct payment data for coverage years that have long since been reconciled. Therefore, consistent with the look-back period for overpayments that are identified by the MA organization or Part D sponsor found at existing §§ 422.326 and 423.360, we are proposing that CMS would request corrections to erroneous payment data only if the erroneous data affects payments for one or more of the 6 most recently completed payment years. That would mean, for example, that after the initial reconciliation takes place for Part D payments under § 423.343 (that is, the determination of the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336) for contract year 2015 (which would take place in 2016), CMS may request corrections to erroneous payment data for contract years 2010 through 2015. We are proposing to use the same 6-year look-back period as applies to plan-identified overpayments under existing §§ 422.326 and 423.360 because both overpayment policies are

intended to address circumstances in which an overpayment has been identified, and we do not believe that the issue of which entity (CMS or the plan) identified the overpayment is relevant to the length of the look-back period.

The timeframes for correcting payment data would be the same as under our current practice for correcting payment data described in existing procedural rules and subregulatory guidance and would be explained in additional procedural rules and subregulatory guidance, as necessary. For example, current Part D guidance states that corrections to PDE data must be completed within 90 days from discovery of the issue. We refer readers to the Health Plan Management System (HPMS) memorandum entitled ''Revision to Previous Guidance Titled 'Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs,' '' dated October 6, 2011.

3. Proposed Payment Offset

If the MA organization or Part D sponsor submits corrected payment data in response to CMS's request pursuant to proposed § 422.330(b) and § 423.352(b), CMS will perform a reconciliation in the payment system using the established payment adjustment process. CMS' systems will conduct a payment reconciliation and determine the associated payment adjustment based on the corrected data using established payment procedures. However, if the MA organization of Part D sponsor fails to correct the erroneous payment data, we are proposing that CMS would conduct a payment offset from plan payments (proposed §§ 422.330(c) and 423.352(c)).

a. Offset Amount

Because the data would not have been corrected in the routine payment process, we are proposing, to be codified at §§ 422.330(c) and 423.352(c), that CMS determine the overpayment offset amount by applying a payment calculation algorithm to simulate the payment calculations currently applied by CMS to produce the routine Part C and Part D payments. The payment calculation algorithm would apply the Part C or Part D payment rules for the applicable year to calculate what the correct payment should have been using corrected payment data. CMS currently simulates payment error amounts for a variety of different purposes including for the annual Part C and Part D error rate reporting (required by the Improper Payment Elimination and Recovery Act (IPERA) and subject to the annual agency's Chief Financial Officer's (CFO) audit and reported in the annual Agency Financial Report (AFR)), RADV payment error estimation (subject to public comment), and the Part C and Part D monthly payment validation required by CFO auditors. These payment error calculations are all conducted outside of the suite of payment systems that CMS uses to make routine payments to MA organizations and Part D sponsors. We believe that these calculations are reliable and an accurate reflection of what the routine payment systems would calculate using the corrected data if the MA organization or Part D sponsor had submitted corrected payment data.

The actual process for calculating the overpayment will be different for Part C and Part D due to the different payment rules for the two programs. The Part C and Part D programs are both subject to risk adjustment payment error resulting from invalid diagnoses and to payment error due to inaccurate enrollment data. The Part D program is further subject to payment reconciliation error resulting from errors in PDE data and/or DIR data. The two programs also are subject to different schedules with regard to the applicable reconciliation date and subsequent payment reconciliation processes.

When new payment-related data are submitted to CMS payment systems, there is generally a change to the correct amount of payment once CMS conducts a payment reconciliation using the established payment adjustment process. However, it is not sufficient for the plan to just submit the new corrected risk adjustment, PDE, or DIR data to CMS systems because data submission does not automatically trigger a system reconciliation and payment adjustment. A change in payment will only occur if a payment reconciliation is conducted. If the applicable reconciliation has already been performed, CMS, at its discretion, may conduct risk adjustment reruns or Part D reopenings to ensure that payments also are corrected to reflect the newly corrected data.

We are proposing that, under the payment calculation algorithm, CMS would calculate the payment to the MA organization or Part D sponsor with and then without the corrected data as of a certain specified date. The difference in the two amounts would be the payment recovery or offset amount. The following are examples of how the offset amount would be calculated for Part C and Part D relative to two different types of payment data errors.

- *Part C Offset Calculation.* The example for Part C relates to incorrect diagnosis data identified by CMS in the process of calculating the national payment error estimate. A beneficiary's final risk score and annual payment will be recalculated outside of the routine payment system without the invalid diagnoses but using all the other data used in the routine payment system. The year-appropriate CMS–HCC risk adjustment software will be used to produce the revised risk scores. The difference in payment for the beneficiary pre- and post-change in the invalid diagnosis will be the offset amount. This offset amount—generated using the same process for each beneficiary for whom erroneous payment data are identified by CMS—will be summed across all beneficiaries.
- *Part D Offset Calculation.* The example for Part D relates to the situation in which a Part D plan sponsor has submitted PDE records for a beneficiary that include invalid National Drug Codes (NDCs). For payment purposes, PDEs are required to reference valid NDCs. In order to calculate the Part D payment offset amount, all of the beneficiary's entire post-reconciliation PDE data will be pulled, and the incorrect PDEs will be deleted or adjusted. The programmed calculation logic will keep track of a variety of payment-related information; for example, a beneficiary's benefit phase, gross covered drug cost, true out-of-pocket (TrOOP) costs, low income cost-sharing subsidies (if any), and plan payment as the beneficiary progresses through the Part D coverage benefit. The calculation algorithm will tap into a variety of different data sets, such as health plan benefit parameters, beneficiary low income subsidy status, and standard low income cost-sharing subsidy parameters. Reports will then be produced on Gross Covered Drug Cost (GCDC) and low income cost-sharing subsidy payment differentials. These payment differential amounts will be incorporated into final reinsurance, low income cost-sharing subsidy, and risk sharing summary totals for a contract. DIR adjustments will be factored into these calculations to arrive at the related payment offset amount to be applied at the contract level. The difference in reinsurance, low income cost-sharing subsidy, and risk sharing dollars with and without the correction to the PDEs will constitute the payment offset related to the beneficiaries with the incorrect PDEs.

If the erroneous payment data in question is subsequently corrected through the CMS payment system, the offset amount will be reversed, and the payment to the MA organization or Part D sponsor will be updated through the

routine payment process. However, if the data in the CMS system are not corrected and CMS conducts a reconciliation or reopening for the applicable payment year after the offset has been determined, the data will not be properly synchronized, and it is possible that the resulting payment adjustments could be incorrect. In order to resolve this problem, CMS may reverse the original offset and recalculate the offset using the more recent data used in the most recent payment reconciliation or reopening. The new offset amount will replace the previous offset amount, and CMS would need to evaluate and act on the resulting overpayment or underpayment.

b. Payment Offset Notification

We are proposing that CMS would provide a payment offset notice to the MA organization or Part D sponsor (proposed §§ 422.330(d)(1) through (d)(3) and 423.352(d)(1) through (d)(3)). The notice would provide the dollar amount to be offset against a plan's monthly prospective payments and an explanation of how the erroneous data were identified and of the calculation of the payment offset amount. Under our proposal, the payment offset notice would also explain that, in the event that the MA organization or Part D sponsor disagrees with the payment offset, it may request an appeal within 30 days of the issuance of the payment offset notice.

4. Proposed Appeals Process for MA Organizations and Part D Sponsors

We are proposing an appeals process for MA organizations and Part D sponsors with three levels of review, including reconsideration (described at proposed §§ 422.330(e)(1) and 423.352(e)(1)), an informal hearing (described at proposed §§ 422.330(e)(2) and 423.352(e)(2)), and an Administrator review (described at proposed §§ 422.330(e)(3) and 423.352(e)(3)).

a. Reconsideration

We are proposing that an MA organization or Part D sponsor must file its request for reconsideration within 30 days from the date that CMS issued the payment offset notice to the MA organization or the Part D sponsor (proposed §§ 422.330(e)(1)(i) and 423.352(e)(1)(i)). At proposed §§ 422.330(e)(1)(ii) and 423.352(e)(1)(ii), we address the information that must be included in the MA organization's or Part D sponsor's request for reconsideration. The request must contain the findings or issues with which the MA organization or Part D sponsor disagrees, the reasons for its disagreement, and any additional documentary evidence that the MA organization or Part D sponsor wishes to submit in support of its position. This additional evidence must be submitted with the request for reconsideration. Any information submitted after this time will be rejected as untimely. In conducting the reconsideration, the CMS reconsideration official reviews the underlying data that were used to determine the amount of the payment offset and any additional documentary evidence that the MA organization or Part D sponsor timely submitted with its reconsideration request (§§ 422.330(e)(1)(iii) and 423.352(e)(1)(iii)). We are proposing at proposed §§ 422.330(e)(1)(iv) and 423.352(e)(1)(iv) that CMS would inform the MA organization or Part D sponsor of its decision. We are proposing at §§ 422.330(e)(1)(v) and 423.352(e)(1)(v) that a reconsideration decision would be final and binding unless a timely request for an informal hearing is filed by the MA organization or Part D sponsor.

b. Informal Hearing

Under our proposal, if the MA organization or Part D sponsor is dissatisfied with CMS' reconsideration decision, it would be entitled to request an informal hearing (proposed §§ 422.330(e)(2) and 423.352(e)(2)). As proposed at §§ 422.330(e)(2)(i) and 423.352(e)(2)(i), a request for an informal hearing must be made in writing and filed within 30 days of the date of CMS' reconsideration decision. The request must include a copy of CMS' reconsideration decision and must specify the findings or issues in the decision with which the MA organization or Part D sponsor disagrees and the reasons for its disagreement (proposed §§ 422.330(e)(2)(ii) and 423.352(e)(2)(ii)).

We set forth the proposed procedures for conducting the informal hearing at proposed §§ 422.330(e)(2)(iii) and 423.352(e)(2)(iii). Under these procedures, CMS would provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date of the hearing (proposed § 422.330(e)(2)(iii)(A) and § 423.352(e)(2)(iii)(A)); the informal hearing would be conducted by a CMS hearing officer. The hearing officer would be limited to reviewing the record that was before CMS when CMS made its reconsideration determination (proposed § 422.330(e)(2)(iii)(B) and § 423.352(e)(2)(iii)(B)). Under our proposal, no new or additional documentation or evidence may be submitted at this hearing. At proposed § 422.330(e)(2)(iii)(C) and § 423.352(e)(2)(iii)(C), we are proposing that the CMS hearing officer would review the record of the proceeding before the CMS reconsideration official using the clearly erroneous standard of review. CMS' reconsideration decision would not be reversed unless the MA organization or Part D sponsor establishes that the decision was clearly erroneous in light of the evidence in the record before the CMS reconsideration official.

At proposed §§ 422.330(e)(2)(iv) and 423.352(e)(2)(iv), we are proposing that the CMS hearing officer would send a written decision of the informal hearing to the MA organization or Part D sponsor explaining the basis for the decision. The CMS hearing officer's decision would be final and binding, unless the decision is reversed or modified by the Administrator (proposed §§ 422.330(e)(2)(v) and 423.352(e)(2)(v)).

c. Review by Administrator

We are proposing that the MA organization or Part D sponsor may request review of the hearing officer's decision by the Administrator within 30 days of issuance of the hearing officer's decision (proposed §§ 422.330(e)(3)(i) and 423.352(e)(3)(i)). The MA organization or Part D sponsor may provide written arguments to the Administrator for review. Under proposed §§ 422.330(e)(3)(ii) and 423.352(e)(3)(ii), after receiving the request to review, the Administrator would have the discretion to elect to review the hearing determination or decline to review it. At proposed §§ 422.330(e)(3)(iii) and 423.352(e)(3)(iii), if the Administrator declines to review the hearing officer's decision, the hearing officer's decision would be final and binding. At proposed §§ 422.330(e)(3)(iv) and 423.352(e)(3)(iv), we are proposing that if the Administrator elects to review the hearing officer's decision, the Administrator would review the hearing officer's decision, as well as any other information included in the record of the hearing officer's decision and any written arguments submitted by the MA organization or Part D sponsor. The Administrator may determine whether to uphold, reverse, or modify the hearing officer's decision. The Administrator's determination would be final and binding (proposed §§ 422.330(e)(3)(v) and 423.352(e)(3)(v)).

5. Matters Subject To Appeal and Burden of Proof

At proposed §§ 422.330(f)(1) and (2) and 423.352(f)(1) and (2), we are proposing to limit the subject-matter that an MA organization or Part D sponsor may appeal under this provision and establish the burden of proof that the MA organization or Part D sponsor must meet in its appeal. Under this provision, an MA organization or Part D sponsor would be able to appeal the notice of payment offset solely on the grounds that CMS' finding that the MA organization's or Part D sponsor's payment data were erroneous was incorrect or otherwise inconsistent with applicable program requirements. The MA organization or Part D sponsor would bear the burden of proof by a preponderance of the evidence in demonstrating that CMS' finding was incorrect or inconsistent with applicable program requirements.

At proposed §§ 422.330(g) and 423.352(g), we are proposing that the appeals process under paragraph (e) of these sections would apply only to payment offsets described at proposed §§ 422.330(c) and 423.352(c). It would not apply to any other CMS payment offset process.

6. Effective Date of Proposed Appeals Process Provisions

We are proposing that this new procedural mechanism for a payment offset at proposed § 422.330 and § 423.352 would apply after the effective date of any final rule implementing the new payment offset and appeals process, but that requests to correct payment data under proposed §§ 422.330(b) and 423.352(b) and the payment offsets under proposed §§ 422.330(c) and 423.352(c) may apply to any payment year, subject to the 6-year limitation under §§ 422.330(b) and 423.352(b).

We are inviting public comment on these proposals.

XVIII. Files Available to the Public via the Internet

Addendum J to this proposed rule is a new addendum that we are proposing for CY 2015, in response to requests by public commenters on the CY 2014 OPPS/ASC final rule with comment period for additional data regarding ratesetting for the new comprehensive APCs established in that final rule with comment period, which are discussed in section II.A.2.e. of this proposed rule. Addendum J lists the HCPCS code pairs for which we are proposing complexity adjustments for CY 2015, by clinical family; the HCPCS codes proposed for exclusion from the comprehensive APC payment bundle; and the relevant cost statistics.

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available only via the Internet on the CMS Web site. To view the Addenda of this proposed rule pertaining to CY 2015 payments under the OPPS, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html;* select ''1613–P'' from the list of regulations. All OPPS Addenda for this proposed rule are contained in the zipped folder entitled ''2015 OPPS 1613–P Addenda'' at the bottom of the page. To view the Addenda of this proposed rule pertaining to the proposed CY 2015 payments under the ASC payment system, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html;* select ''1613–P'' from the list of regulations. All ASC Addenda for this proposed rule are contained in the zipped folders entitled ''Addendum AA, BB, DD1 and DD2,'' and ''Addendum EE'' at the bottom of the page.

XIX. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and to 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 Paperwork Reduction Act 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 comments on each of the issues outlined above for the information collection requirements discussed below.

B. Requirements in Regulation Text: Proposed Changes to the Rural Provider and Hospital Ownership Exceptions to the Physician Self-Referral Law: Expansion Exception Process (§ 411.362)

Section XV.C. of the preamble of this proposed rule discusses our proposal to revise the expansion exception process for physician-owned hospitals under the rural provider and hospital ownership exceptions to the physician self-referral law. Specifically, we are proposing to revise 42 CFR 411.362(c) to permit physician-owned hospitals to use data from HCRIS, internal data sources, or external data sources to estimate the percentages of inpatient Medicaid admissions and to determine the bed capacities and the bed occupancy rates referenced in that section for the hospitals to demonstrate eligibility for an expansion exception.

We believe the burden associated with this revision is exempt from the PRA under 5 CFR 1320.3(c), which defines the agency collection of information subject to the requirements of the PRA as information collection imposed on 10 or more persons within any 12-month period. We do not believe this information collection impacts 10 or more entities in a 12-month period. We have received four requests since the expansion exception process was implemented on February 1, 2012; only one of the four requests was complete and eligible to proceed in the process. In CYs 2012, 2013, and 2014, we received zero, two, and two requests, respectively.

C. Associated Information Collections Not Specified in Regulatory Text

In this proposed rule, we make reference to proposed associated information collection requirements that were not discussed in the regulation text contained in this proposed rule. The following is a discussion of those requirements.

1. Hospital OQR Program

As we stated in section XIV. of the CY 2012 OPPS/ASC final rule with comment period, the Hospital OQR Program has been generally modeled after the quality data reporting program for the Hospital IQR Program (76 FR 74451). We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72111 through 72114), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74549 through 74554), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68527 through 68532) and the CY 2014 OPPS/ASC final rule with comment period (78

FR 75170 through 75172) for detailed discussions of the Hospital OQR Program information collection requirements we have previously finalized.

a. Revisions to the CY 2016 Payment Determination Estimates

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75103), we finalized the adoption of four new measures for the CY 2016 payment determination and subsequent years: (1) OP–27: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431); (2) OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); (3) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); and (4) OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536). In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we estimated measures OP–29, OP–30 and OP–31 would require 40 hours of reporting per quarter (96 cases × 0.417 hours). We also estimated that reporting these measures via our Web-based tool would take 10 minutes (or 0.167 hours) per measure per year (or 2.5 minutes for each quarter's worth of data, which is submitted on an annual basis) (78 FR 75171 through 75172).

As stated in section XIII.D.2. of this proposed rule, we delayed reporting for OP–29 and OP–30 by one quarter. Therefore, we estimate a reduction in burden of 40 hours for each of these measures (40 hours per quarter for reporting + 2.5 minutes of reporting via the Web-based tool) per hospital for the CY 2016 payment determination. In addition, in section XIII.D.3. of this proposed rule, we are proposing to exclude this measure from the CY 2016 payment determination measure set. Therefore, we estimate that there will be no burden for reporting OP–31 for the CY 2016 payment determination, and an overall reduction in burden of 160 hours ((40 hours per quarter for reporting × 4 quarters) + 0.167 hours per year for reporting via the Web-based tool) per hospital for the CY 2016 payment determination because of this proposal.

Combining the estimated reductions in burden for all three of these measures, we estimate a total reduction in burden of 240 hours (40 hours + 40 hours + 160 hours) per hospital for the CY 2016 payment determination due to delayed data collection and the proposed measure exclusion. We estimate that approximately 3,300 hospitals will participate in the Hospital OQR Program for the CY 2016 payment determination. Therefore, we estimate a total reduction in burden of 792,000 hours (240 hours × 3,300 hospital) for all hospitals participating in the Hospital OQR Program for the CY 2016 payment determination based on the data collection delays for OP–29, OP–30, and OP–31. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we estimated that these measures would result in a financial burden of $30 per hour. Therefore, we estimate that the delay of these three measures will result in a reduction of $23.8 million ($30/hour × 792,000 hours).

b. Hospital OQR Program Requirements for the CY 2017 Payment Determination and Subsequent Years

As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we believe there is a burden associated with successful participation in the Hospital OQR Program, where successful participation results in a full annual payment update (APU) for the particular payment determination. For the reasons stated in that rule, we believe that the burden associated with these requirements is 42 hours per hospital or 138,600 hours for all hospitals. We estimate a financial burden for these requirements of $4.2 million ($30/hour × 138,600) for all hospitals.

(1) Claims-Based Measures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530) for detailed discussions of the information collection requirements for the previously finalized claims-based measures (OP–8, OP–9, OP–10, OP–11, OP–13, OP–14, and OP–15). In section XIII.E. of this proposed rule, we are proposing to adopt one additional claims-based measure for the CY 2017 payment determination and subsequent years: OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. As we note in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530), we calculate the claims-based measures using Medicare FFS claims data that do not require additional hospital data submissions.

(2) Chart-Abstracted Measures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530 through 68531) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171) for detailed discussions of the information collection requirements for the previously finalized chart-abstracted measures (OP–1, OP–2, OP–3, OP–4, OP–5, OP–6, OP–7, OP–18, OP–20, OP–21, OP–22, OP–23, OP–29, OP–30, and OP–31).

In section XIII. of this proposed rule, we are proposing to remove three chart-abstracted measures from the Hospital OQR Program for the CY 2017 payment determination and subsequent years: OP–4: Aspirin at Arrival (NQF #0286); OP–6: Timing of Prophylactic Antibiotics; and OP–7: Perioperative Care: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528). We previously estimated that each participating hospital will spend 35 minutes (or 0.583 hours) per case to collect and submit the data required for the chart-abstracted measures finalized for the CY 2015 payment determination and subsequent years (OP–1, OP–2, OP–3, OP–4, OP–5, OP–6, OP–7, OP–18, OP–20, OP–21, OP–22, OP–23) for each case (78 FR 75171). Since we are proposing to remove three of these measures, we believe that the time to chart-abstract these measures will be reduced by 25 percent (3 of 12 measures). Therefore, we estimate that hospitals will spend approximately 26 minutes (0.433 hours) per case to collect and submit these data.

Data submitted for the CY 2014 payment determination indicate that a hospital will submit approximately 1,266 cases per year for these measures. Therefore, we estimate that the time it will take a hospital to abstract data for all of the chart-abstracted measures will be 549 hours per year (1,266 cases × 0.433 hours). We estimate that there will be approximately 3,300 hospitals that participate in the Hospital OQR Program for the CY 2017 payment determination and subsequent years. Therefore, we estimate that the chart-abstracted measures for the CY 2017 payment determination and subsequent years will result in a burden of 1.8 million hours (549 hours × 3,300 hospitals) for all participating hospitals, for a total financial burden of approximately $54 million (1.8 million hours × $30/hour).

In addition, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we estimated that OP–29 and OP–30 would require 25 minutes (0.417

hours) per case per measure to chart-abstract. We also estimated that hospitals would abstract 384 cases per year for each of these measures. Our estimate for the CY 2017 payment determination and subsequent years has not changed from last year's estimate (although, as noted above, we have changed our estimate for the CY 2016 payment determination based on the delay of OP–29 and OP–30). Therefore, for the CY 2017 payment determination and subsequent years, we estimate a burden of 1.1 million hours (3,300 hospitals × 0.417 hours/case × 384 case/measure × 2 measures) for all participating hospitals for OP–29 and OP–30 for a total financial burden of approximately $33 million ($30/hour × 1.1 million hours).

In section XIII.D.3. of this proposed rule, we are proposing to exclude OP–31 from the CY 2016 payment determination measure set and, for the CY 2017 payment determination and subsequent years, to change this measure from required to voluntary. Hospitals would not be subject to a payment reduction with respect to this measure for the CY 2016 payment determination or during the period of voluntary reporting. We continue to believe this measure addresses an important area of care, and anticipate that many facilities will report this measure on a voluntary basis. In the CY 2014 ASC/OPPS final rule with comment period (78 FR 75171), we estimated that OP–31 would require 25 minutes (0.417 hours) per case to chart-abstract. We also estimated that hospitals would abstract 384 cases per year for this measure. We estimate that approximately 20 percent of hospitals (660 hospitals (3,300 hospitals × 0.2)) will elect to report this measure on a voluntary basis. Therefore, we are revising the estimated burden for this measure to 105,685 hours (660 hospitals × 0.417 hours/case × 384 cases) for participating hospitals for the CY 2017 payment determination and subsequent years, for a total financial burden of approximately $3.2 million ($30/hour × 105,685 hours).

Therefore, for the chart-abstracted measures, we estimate a total burden for all participating hospitals of 3 million hours (1.8 million hours + 105,685 hours + 1.1 million hours) and $90 million (3 million hours × $30/hour) for the CY 2017 payment determination and subsequent years.

(3) Web-Based Measures Submitted Directly to CMS for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171) for detailed discussions of the information collection requirements for the previously finalized measures submitted via the Web-based tool. For the reasons stated in that final rule with comment period, we estimate that each participating hospital would spend 10 minutes per measure per year to collect and submit the data for the six measures (OP–12, OP–17, OP–25, OP–26, OP–29, and OP–30) submitted via the Web-based tool. Therefore, the estimated annual estimate burden associated with these measures for all participating hospitals is 3,307 hours (3,300 hospitals × 0.167 hours/measure × 6 measures/hospital) for the CY 2017 payment determination and subsequent years.

As stated above, in section XIII.D.3. of this proposed rule, we are proposing to require voluntary reporting for OP–31, meaning that failing to report this measure would not affect a hospital's CY 2017 and subsequent years' payment determinations. We estimate that approximately 20 percent of hospitals (660 hospitals (3,300 hospitals × 0.2)) will elect to report this measure on a voluntary basis. Therefore, we are revising the estimated burden for this measure for all participating hospitals to 111 hours (660 hospitals × 0.167 hours) for the CY 2017 payment determination and subsequent years.

Therefore, we estimate that the financial burden incurred for the Web-based submission of these measures for all participating hospitals will be $119,070 ($30/hour × (3,858 hours + 111 hours)) for the CY 2017 payment determination and subsequent years.

(4) NHSN HAI Measure for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172) for detailed discussions of the information collection requirements for OP–27: Influenza Vaccination Coverage among Healthcare Personnel. In section XIII.D.1. of this proposed rule, we are proposing to correct a submission deadline for this measure. We do not believe there will be a change in burden due to this proposal since it was a typographical error and our previous estimates were based on the corrected submission timeframe. We also noted that hospitals may report this measure for both the Hospital IQR Program and the Hospital OQR Program by CCN. Although we believe an overall reduction in burden will occur from this guidance because hospitals will only be required to submit this information once for each program, submitting this information is still a requirement of the Hospital OQR Program. Therefore, we do not believe this guidance will result in a reduction in burden attributable to the Hospital OQR Program. Therefore, for the reasons discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172), we estimate a total burden for all participating hospitals of 106,940 hours and a total financial burden of $3,208,203 associated with this measure.

c. Review and Corrections Period Requirements for the CY 2017 Payment Determination and Subsequent Years

In section XIII.H.2.f. of this proposed rule, we are proposing to formalize that the time during which hospitals submit chart-abstracted data is the review and corrections period for that data. Because this proposal does not require hospitals to submit additional data, we do not believe it will increase burden for these hospitals.

d. Hospital OQR Program Validation Requirements for the CY 2017 Payment Determination and Subsequent Years

In section XIII.H.3.d. of this proposed rule, we are proposing three changes to our validation procedures: (1) We are proposing to change the eligibility requirements for hospitals selected for validation so that a hospital would be eligible if it submits at least one case to the Hospital OQR Program Clinical Data Warehouse during the quarter containing the most recently available data; (2) we are proposing to give hospitals the option to either submit paper copies of patient charts or securely transmit electronic versions of medical information for validation; and (3) we are proposing that a hospital must identify the medical record staff responsible for submission of records under the Hospital OQR Program to the designated CMS contractor. We do not believe that changing the eligibility requirements will result in additional burden since the same number of hospitals will be selected for validation, as discussed below. In addition, we do not believe that changing to whom a hospital must identify the medical staff responsible for submission of records will result in additional burden since hospitals must already submit this data; that is, only the contractor to whom the data is submitted may change. We do believe, however, that the second

requirement may result in a change in burden.

We are proposing that the requirement to submit patient charts for validation of Hospital OQR Program data may be met by employing either of the following options: (1) A hospital may submit paper medical records, the form in which we have historically requested them; or (2) a hospital may securely transmit electronic versions of medical information beginning in the CY 2017 payment determination. We are proposing that hospitals that chose to securely transmit electronic versions of medical information should either: (1) Download or copy the digital image of the patient chart onto CD, DVD, or flash drive and ship the electronic media following instructions specified on the QualityNet Web site; or (2) securely submit digital images (PDFs) of patient charts using a Secure File Transfer Portal on the QualityNet Web site. In the FY 2014 IPPS/LTCH PPS final rule, the Hospital IQR Program previously finalized a similar policy that also allows hospitals to submit electronic versions of records for validation using the first method (78 FR 50834 through 78 FR 50835). The Hospital IQR Program has proposed the second method, secure submission of digital images via a Secure File Transfer Portal, in the FY 2015 IPPS/LTCH proposed rule (79 FR 28251). For the same reasons outlined in the Hospital IQR Program (78 FR 50956), we are proposing a reimbursement rate of $3.00 per patient chart submitted electronically (using either of the proposed methods for electronic submission) for validation for the CY 2017 payment determination and subsequent years. We will continue to reimburse hospitals at a rate of 12 cents per page, plus shipping, for records provided on paper (76 FR 74577).

The burden associated with validation is the time and effort necessary to submit validation data to the CMS contractor. For some hospitals, we believe that submitting this data electronically may result in a reduction in burden; for others we believe that submitting paper copies will be the least burdensome option. We sample 500 hospitals for validation, and we estimate that it will take each hospital 12 hours to comply with the data submission requirements. Therefore, we estimate a total burden of approximately 6,000 hours (500 hospitals × 12 hours/hospital) and a total financial impact of $180,000 ($30/hour × 6,000 hours) for the CY 2017 payment determination and subsequent years.

e. Extraordinary Circumstances Extensions or Exemptions Process

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances extension or waiver process under the Hospital OQR Program. In this proposed rule, we are proposing to make a change from the phrase ''extension or waiver'' to the phrase ''extension or exemption'' throughout the regulation. We do not anticipate that this proposed minor change will affect the collection of information burden estimates for this process.

f. Reconsideration and Appeals

While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 regulations excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

We invite public comment on the burden associated with these information collection requirements.

2. ASCQR Program Requirements

a. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH final rule (77 FR 53672), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532 through 68533), and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75174) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized.

b. Revisions to the CY 2016 Payment Determination Estimates

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75130), we finalized the adoption of three new measures for the CY 2016 payment determination and subsequent years: ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658), ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659), and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536). In that rule, we estimated that each participating ASC would spend 35 minutes per case to collect and submit the data for these measures, making a total estimated burden for ASCs with a single case per ASC of 3,067 hours (5,260 ASCs × 0.583 hours per case per ASC). We also stated that we expected ASCs would vary greatly as to the number of cases per ASC due to ASC specialization (78 FR 75173). As stated in section XIV.E.3. of this proposed rule, we have delayed reporting for ASC–9 and ASC–10 by one quarter. Therefore, we estimate a 25-percent reduction in cases and burden for these measures for the CY 2016 payment determination. As stated in section XIV.E.3.c. of this proposed rule, we delayed reporting of ASC–11 by one year and are proposing to exclude ASC–11 from the CY 2016 payment determination measure set . As a result, we do not believe there would be any burden associated with this measure for the CY 2016 payment determination.

c. Claims-Based Measures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532) and CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75174) for detailed discussions of the information collection requirements for the five previously-adopted claims-based ASCQR Program measures (four outcome measures and one process measure). The five previously adopted measures are: ASC–1: Patient Burn (NQF #0263); ASC–2: Patient Fall (NQF #0266); ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); ASC–4: Hospital Transfer/Admission (NQF #0265); and ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264). For the reasons we discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75173), we estimate that the reporting burden to report Quality Data Codes (QDCs) for these five claims-based outcome measures would be nominal for the CY 2017 payment determination and for subsequent years.

In section XIV.B.5. of this proposed rule, we are proposing to add one additional claims-based measure to the ASCQR Program. The additional measure, ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, would be computed by CMS based on Medicare FFS claims, and would not require ASCs to input QDCs. Therefore, we do not anticipate that this proposed

measure would add additional burden to ASCs for the CY 2017 payment determination and for subsequent years.

d. Web-Based Measures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532) and CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75174) for detailed discussions of the information collection requirements for the five previously-adopted Web-based measures, excluding ASC–11, which we are proposing for voluntary inclusion in the ASCQR Program for CY 2017. The five previously adopted measures are: ASC–6: Safe Surgery Checklist Use; ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures; ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); and ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659).

For the reasons we discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for the ASC–6: Safe Surgery Checklist Use and the ASC–7: ASC Facility Volume measures would be 1,756 hours (5,260 ASCs × 2 measures × 0.167 hours per ASC) and $52,680 (1,756 hours × $30.00 per hour) annually for the CY 2017 payment determination and for subsequent years.

For the reasons discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for the ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure would be 18,005 hours and $540,150 (18,005 hours × $30.00 per hour) annually for the CY 2017 payment determination and for subsequent years.

For the reasons discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for ASCs with a single case per ASC for the chart-abstracted ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) and ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) measures would be 3,067 hours and $92,010 (3,067 hours × $30.00 per hour) annually for the CY 2017 payment determination and for subsequent years.

In section XIV.E.3.c. of this proposed rule, we are proposing that data collection and submission be voluntary for ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536), meaning we would not subject ASCs to payment reduction with respect to this measure during the period of voluntary reporting. We continue to believe this measure addresses an important area of care, and anticipate that many facilities will report this measure on a voluntary basis. In the CY 2014 ASC/OPPS final rule with comment period (78 FR 75173), we estimated that each participating ASC would spend 35 minutes per case to collect and submit the data for this measure, making the total estimated burden for ASCs with a single case per ASC of 3,067 hours (5,260 ASCs × 0.583 hours per case per ASC) annually. We expect that ASCs would vary greatly as to the number of cases per ASC due to ASC specialization. We estimate that approximately 20 percent of ASCs would elect to report this measure on a voluntary basis; therefore, we estimate the total estimated burden for ASCs with a single case per ASC to be 613 hours (1,052 ASCs × 0.583 hours per case per ASC) and $18,390 (613 hours × $30.00 per hour) annually for the CY 2017 payment determination and subsequent years.

e. Extraordinary Circumstances Extension or Exemptions Process

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75140) for a complete discussion of our extraordinary circumstances extension or waiver process under the ASCQR Program. We are not proposing to make any substantive changes to this process. However, in the future, we will refer to the process as the extraordinary circumstances extensions or exemptions process. In section XIV.E.7. of this proposed rule, we note that we are proposing to make certain changes to the form to ensure that the form is consistent across CMS quality reporting programs. We do not anticipate that these proposed minor changes will affect the burden estimates for this process.

f. Reconsideration and Appeals

While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 regulations excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

We invite public comment on the burden associated with these information collection requirements.

XX. 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.

XXI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

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 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104–121) (5 U.S.C. 804(2)). This section of the proposed rule contains the impact and other economic analyses for the provisions that we are proposing.

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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104–121). Accordingly, this proposed rule has been reviewed by the Office of Management and Budget. We

have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this proposed rule. We are soliciting public comments on the regulatory impact analysis provided.

2. Statement of Need

This proposed rule is necessary to update the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2015. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are proposing to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2013, through and including December 31, 2013, and updated cost report information.

This proposed rule also is necessary to update the ASC payment rates for CY 2015, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2015. Because ASC payment rates are based on the OPPS relative payment weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC not less frequently than every 2 years.

3. Overall Impacts for the Proposed OPPS and ASC Payment Provisions

We estimate that the total increase in Federal government expenditures under the OPPS for CY 2015 compared to CY 2014 due to the changes in this proposed rule would be approximately $800 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the proposed OPPS expenditures for CY 2015 would be approximately $5.224 billion higher relative to expenditures in CY 2014. Because this proposed rule is economically significant as measured by the threshold of an additional $100 million in expenditures in one year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 52 displays the redistributional impact of the proposed CY 2015 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the proposed update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through estimates, and the application of the proposed frontier State wage adjustment for CY 2015) would increase total OPPS payments by 2.1 percent in CY 2015. The proposed changes to the APC weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase OPPS payments because these proposed changes to the OPPS are budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2014 and CY 2015, considering all proposed payments, including proposed changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the proposed OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, would increase total estimated OPPS payments by 2.2 percent.

We estimate the total increase (from proposed changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in expenditures under the ASC payment system for CY 2015 compared to CY 2014 to be approximately $243 million. Because the provisions for the ASC payment system are part of a proposed rule that is economically significant as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the proposed changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of the proposed rule. Tables 53 and Table 54 of this proposed rule display the redistributional impact of the proposed CY 2015 changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Estimated Effects of Proposed OPPS Changes in This Proposed Rule

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2015 policy changes on various hospital groups. We post on the CMS Web site our proposed hospital-specific estimated payments for CY 2015 with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1613–P'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 52 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our proposed policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service-mix, or number of encounters. In this proposed rule, we are soliciting public comment and information about the anticipated effects of our proposed changes on providers and our methodology for estimating them. Any public comments that we receive will be addressed in the applicable sections of the final rule with comment period.

(2) Estimated Effects of Proposed OPPS Changes on Hospitals

Table 52 below shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the proposed change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We now include a second line for all hospitals, excluding

permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 52, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2015, we are continuing to pay CMHCs under APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), and we are paying hospitals for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B. of this proposed rule.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase for FY 2015 is 2.7 percent (79 FR 28087). Section 1833(t)(3)(F)(i) of the Act reduces that 2.7 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.4 percentage points for FY 2015 (which is also the proposed MFP adjustment for FY 2015 in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28087); and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(iv) of the Act further reduce the market basket percentage increase by 0.2 percentage points, resulting in the proposed OPD fee schedule increase factor of 2.1 percent. We are proposing to use the proposed OPD fee schedule increase factor of 2.1 percent in the calculation of the CY 2015 proposed OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.00. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2015 estimates in Table 52.

To illustrate the impact of the proposed CY 2015 changes, our analysis begins with a baseline simulation model that uses the CY 2014 relative payment weights, the FY 2014 final IPPS wage indexes that include reclassifications, and the final CY 2014 conversion factor. Table 52 shows the estimated redistribution of the proposed increase in payments for CY 2015 over CY 2014 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2014 and CY 2015 (Column 2); the proposed wage indexes and the provider adjustments (Column 3); the combined impact of all the proposed changes described in the preceding columns plus the proposed 2.1 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the combined impact shown in Column 4 plus the proposed CY 2015 frontier State wage index adjustment (Column 5); and the estimated impact taking into account all proposed payments for CY 2015 relative to all payments for CY 2014, including the impact of proposed changes in estimated outlier payments and proposed changes to the pass-through payment estimate (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to maintain the current adjustment percentage for CY 2015. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2015 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also would depend on changes in volume, practice patterns, and the mix of services billed between CY 2014 and CY 2015 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2015 would increase Medicare OPPS payments by an estimated 2.2 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 2.2 percent increase in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 52 shows the total number of facilities (3,947), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2013 hospital outpatient and CMHC claims data to model CY 2014 and CY 2015 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2014 or CY 2015 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a disproportionate share (DSH) variable for hospitals not participating in the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,814), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on 72 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Proposed Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals would experience a decrease of −0.1 percent, with the impact ranging from an increase of 0.1 percent to a decrease of −0.3 percent, depending on the number of beds. Rural hospitals would experience an increase

of 0.5 percent, with the impact ranging from an increase of 1.2 percent to a decrease of −0.6 percent, depending on the number of beds. Major teaching hospitals would experience an increase of 0.6 percent overall.

Column 3: New Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the proposed APC recalibration; the proposed updates for the wage indexes with the proposed fiscal year (FY) 2015 IPPS post-reclassification wage indexes; and the proposed rural adjustment. We modeled the independent effect of the proposed budget neutrality adjustments and the proposed OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2014 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the proposed updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the proposed frontier State wage index adjustment, which is not budget neutral and is included in Column 5. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2015, as described in section II.E. of this proposed rule.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the proposed CY 2015 scaled weights and a CY 2014 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indexes between CY 2014 and CY 2015. The proposed FY 2015 wage policy results in modest redistributions.

There is no difference in impact between the CY 2014 cancer hospital payment adjustment and the proposed CY 2015 cancer hospital payment adjustment because we are proposing the same payment-to-cost ratio target in CY 2015 as in CY 2014.

Column 4: All Proposed Budget Neutrality Changes Combined With the Proposed Market Basket Update

Column 4 demonstrates the combined impact of all the proposed changes previously described and the proposed update to the conversion factor of 2.1 percent. Overall, these changes would increase payments to urban hospitals by 2.1 percent and to rural hospitals by 2.4 percent. Most classes of hospitals would receive an increase in line with the proposed 2.1 percent overall increase after the update is applied to the budget neutrality adjustments.

Column 5: All Proposed Adjustments With the Proposed Frontier State Wage Index Adjustment

This column shows the impact of all proposed budget neutrality adjustments, application of the proposed 2.1 percent OPD fee schedule increase factor, and the nonbudget-neutral impact of applying the proposed CY 2015 frontier State wage adjustment. Rural hospitals in West North Central and Mountain States would experience estimated increases in payment of 3.8 and 4.3 percent, respectively, as a result of the proposed frontier State wage index adjustment, while urban hospitals in those States would experience estimated increases of 3.2 and 2.5 percent, respectively.

Column 6: All Proposed Changes for CY 2015

Column 6 depicts the full impact of the proposed CY 2015 policies on each hospital group by including the effect of all of the proposed changes for CY 2015 and comparing them to all estimated payments in CY 2014. Column 6 shows the combined budget neutral effects of Column 2 and 3; the proposed OPD fee schedule increase; the impact of the proposed frontier State wage index adjustment; the impact of estimated OPPS outlier payments as discussed in section II.G. of this proposed rule; the proposed change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIII. of this proposed rule); and the difference in total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2014 update (and assumed, for modeling purposes, to be the same number for CY 2015), we included 35 hospitals in our model because they had both CY 2013 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2015 would increase payments to all providers by 2.2 percent for CY 2015. We modeled the independent effect of all proposed changes in Column 6 using the final relative payment weights for CY 2014 and the proposed relative payment weights for CY 2015. We used the final conversion factor for CY 2014 of $72.672 and the proposed CY 2015 conversion factor of $74.176 discussed in section II.B. of this proposed rule.

Column 6 contains simulated outlier payments for each year. We used the 1-year proposed charge inflation factor used in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28321) of 5.57 percent (1.0557) to increase individual costs on the CY 2013 claims, and we used the most recent overall CCR in the April 2014 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2014. Using the CY 2013 claims and a 5.57 percent charge inflation factor, we currently estimate that outlier payments for CY 2014, using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $2,900 would be approximately 0.9 percent of total payments. The estimated current outlier payments of 0.9 percent are incorporated in the comparison in Column 6. We used the same set of claims and a proposed charge inflation factor of 11.46 percent (1.1146) and the CCRs in the April 2014 OPSF, with an adjustment of 0.9813, to reflect relative changes in cost and charge inflation between CY 2013 and CY 2015, to model the CY 2015 proposed outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $3,100. The charge inflation and CCR inflation factors are discussed in detail in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28321).

We estimate that the anticipated change in payment between CY 2014 and CY 2015 for the hospitals failing to meet the Hospital OQR Program requirements would be negligible. Overall, we estimate that facilities would experience an increase of 2.2 percent under this proposed rule in CY 2015 relative to total spending in CY 2014. This projected increase (shown in Column 6) of Table 52 reflects the proposed 2.1 percent OPD fee schedule increase factor, less 0.01 percent for the proposed change in the pass-through estimate between CY 2014 and CY 2015, plus 0.1 percent for the difference in estimated outlier payments between CY 2014 (0.9 percent) and CY 2015 (1.0 percent), less 0.1 percent due to the frontier adjustment in CY 2014, plus 0.1 percent due to the proposed frontier State wage index adjustment in CY 2015. We estimate that the combined effect of all proposed changes for CY 2015 would increase payments to urban hospitals by 2.2 percent.

Overall, we estimate that rural hospitals would experience a 2.5 percent increase as a result of the

combined effects of all proposed changes for CY 2015. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services would experience a decrease of −3.1 percent and rural hospitals that bill 11,000 or more lines of OPPS services would experience increases ranging from 1.5 to 3.0 percent.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all proposed changes would include an increase of 2.9 percent for major teaching hospitals and 2.1 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 1.8 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 2.4 percent, proprietary hospitals would experience an increase of 1.7 percent, and governmental hospitals would experience an increase of 2.2 percent.

TABLE 52—ESTIMATED IMPACT OF THE PROPOSED CY 2015 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	APC Recalibration (all proposed changes)	Proposed new wage index and provider adjustments	All budget neutral changes (combined cols 2,3) with proposed market basket update	All proposed budget neutral changes and proposed update (column 4) with proposed frontier wage index, adjustment	All proposed changes
	(1)	(2)	(3)	(4)	(5)	(6)
ALL FACILITIES *	3,947	0.0	0.0	2.1	2.2	2.2
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,814	0.0	0.0	2.1	2.2	2.2
URBAN HOSPITALS	2,953	−0.1	0.0	2.1	2.2	2.2
LARGE URBAN (GT 1 MILL.)	1,616	−0.1	0.1	2.2	2.2	2.3
OTHER URBAN (LE 1 MILL.)	1,337	−0.1	−0.1	1.9	2.2	2.1
RURAL HOSPITALS	861	0.5	−0.2	2.4	2.7	2.5
SOLE COMMUNITY	377	0.7	−0.1	2.6	3.0	2.7
OTHER RURAL	484	0.3	−0.3	2.2	2.3	2.2
BEDS (URBAN):						
0–99 BEDS	1,008	0.1	0.1	2.4	2.6	2.5
100–199 BEDS	856	0.2	0.0	2.3	2.4	2.4
200–299 BEDS	462	−0.2	0.1	2.0	2.2	2.2
300–499 BEDS	412	−0.3	0.0	1.8	2.0	2.0
500 + BEDS	215	0.1	0.0	2.1	2.1	2.3
BEDS (RURAL):						
0–49 BEDS	338	0.9	0.0	3.0	3.2	3.0
50–100 BEDS	319	1.2	−0.2	3.0	3.3	3.1
101–149 BEDS	117	0.3	−0.1	2.3	2.6	2.4
150–199 BEDS	47	0.0	−0.5	1.6	2.3	1.7
200 + BEDS	40	−0.6	−0.2	1.3	1.3	1.4
VOLUME (URBAN):						
LT 5,000 Lines	500	−2.6	−0.2	−0.8	−0.6	−0.7
5,000–10,999 Lines	138	−2.7	−0.1	−0.7	−0.1	−0.5
11,000–20,999 Lines	120	−2.4	0.0	−0.3	−0.1	−0.1
21,000–42,999 Lines	237	−0.4	0.1	1.8	1.8	1.9
42,999–89,999 Lines	540	−0.2	0.0	1.9	1.9	2.0
GT 89,999 Lines	1,418	0.0	0.0	2.1	2.2	2.3
VOLUME (RURAL):						
LT 5,000 Lines	35	−5.1	−0.1	−3.1	−0.3	−3.1
5,000–10,999 Lines	27	−4.1	0.1	−1.9	−0.7	−1.9
11,000–20,999 Lines	50	−0.2	−0.4	1.5	1.7	1.5
21,000–42,999 Lines	162	1.0	−0.1	3.0	3.5	3.0
GT 42,999 Lines	587	0.5	−0.2	2.4	2.6	2.5
REGION (URBAN):						
NEW ENGLAND	151	1.3	−0.1	3.3	3.3	3.4
MIDDLE ATLANTIC	357	0.5	0.5	3.1	3.1	3.2
SOUTH ATLANTIC	468	−0.2	−0.2	1.6	1.6	1.8
EAST NORTH CENT.	465	0.1	−0.3	1.9	1.9	2.1
EAST SOUTH CENT.	175	−1.0	−0.5	0.6	0.6	0.8
WEST NORTH CENT.	192	−0.1	0.0	2.0	3.2	2.1
WEST SOUTH CENT.	509	−1.1	−0.2	0.8	0.8	1.0
MOUNTAIN	199	0.0	0.0	2.1	2.5	2.3
PACIFIC	390	−0.1	1.0	3.1	3.1	3.2
PUERTO RICO	47	1.0	0.5	3.6	3.6	3.6
REGION (RURAL):						
NEW ENGLAND	23	2.0	−0.1	4.0	4.0	4.1
MIDDLE ATLANTIC	58	1.4	0.4	3.9	3.9	4.0
SOUTH ATLANTIC	130	−0.3	−0.5	1.3	1.3	1.4

TABLE 52—ESTIMATED IMPACT OF THE PROPOSED CY 2015 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC Recalibration (all proposed changes)	Proposed new wage index and provider adjustments	All budget neutral changes (combined cols 2,3) with proposed market basket update	All proposed budget neutral changes and proposed update (column 4) with proposed frontier wage index adjustment	All proposed changes
	(1)	(2)	(3)	(4)	(5)	(6)
EAST NORTH CENT.	120	0.7	0.0	2.8	2.8	2.9
EAST SOUTH CENT.	165	−0.2	−0.4	1.5	1.5	1.6
WEST NORTH CENT.	99	0.7	−0.2	2.6	3.8	2.6
WEST SOUTH CENT.	181	0.1	−0.6	1.6	1.6	1.7
MOUNTAIN	61	0.9	−0.5	2.6	4.3	2.8
PACIFIC	24	1.4	0.9	4.4	4.4	4.4
TEACHING STATUS:						
NON-TEACHING	2,793	−0.1	0.0	2.0	2.1	2.1
MINOR	699	−0.3	−0.1	1.7	1.9	1.8
MAJOR	322	0.6	0.1	2.8	2.8	2.9
DSH PATIENT PERCENT:						
0	15	0.2	0.5	2.8	3.2	2.8
GT 0–0.10	334	0.3	0.2	2.6	2.8	2.7
0.10–0.16	317	0.3	−0.1	2.4	2.5	2.4
0.16–0.23	681	0.2	−0.1	2.3	2.4	2.4
0.23–0.35	1,095	0.0	0.0	2.1	2.3	2.2
GE 0.35	811	−0.2	0.0	1.9	1.9	2.1
DSH NOT AVAILABLE**	561	−6.6	0.1	−4.4	−4.4	−4.5
URBAN TEACHING/DSH:						
TEACHING & DSH	928	0.1	0.0	2.2	2.3	2.3
NO TEACHING/DSH	1,482	−0.2	0.1	2.0	2.1	2.1
NO TEACHING/NO DSH	13	0.2	0.5	2.9	2.9	2.9
DSH NOT AVAILABLE**	530	−6.1	0.2	−3.8	−3.8	−3.9
TYPE OF OWNERSHIP:						
VOLUNTARY	2,007	0.1	0.0	2.2	2.4	2.4
PROPRIETARY	1,255	−0.5	0.0	1.6	1.7	1.7
GOVERNMENT	552	0.0	−0.1	2.1	2.1	2.2
CMHCs	72	−4.0	−0.1	−2.0	−2.0	−1.6

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2015 OPPS policies and compares those to the CY 2014 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2015 hospital inpatient wage index, including all proposed hold harmless policies and transitional wages. The proposed rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the proposed cancer hospital adjustment is 1.000 because the payment-to-cost ratio target remains the same as in CY 2014.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.1 percent OPD fee schedule update factor (2.7 percent reduced by 0.4 percentage points for the final productivity adjustment and further reduced by 0.2 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (5) shows the non-budget neutral impact of applying the frontier State wage adjustment in CY 2015.

Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, adding estimated outlier payments, and applying payment wage indexes.

* These 3,947 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

(3) Estimated Effects of Proposed OPPS Changes on CMHCs

The last line of Table 52 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2014, CMHCs are paid under two APCs for these services: APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs). Hospitals are paid for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). We use our standard ratesetting methodology to derive the payment rates for each APC based on the cost data derived from claims and cost reports for the provider-type-specific APC. For CY 2015, we are proposing to continue the provider-type-specific APC structure that we adopted in CY 2011. We modeled the impact of this proposed APC policy assuming that CMHCs would continue to provide the same number of days of PHP care, with each day having either 3 services or 4 or more services, as seen in the CY 2013 claims data used for this proposed rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs would experience an overall −1.6 percent decrease in payments from CY 2014 (shown in Column 6).

Column 3 shows that the estimated impact of adopting the proposed FY 2015 wage index values would result in a small decrease of −0.1 percent to CMHCs. We note that all providers paid under the OPPS, including CMHCs, would receive a 2.1 percent OPD fee schedule increase factor. Column 4 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2015 and the proposed FY 2015 wage index updates, would result in an estimated decrease of −2.0 percent. Column 5 shows that adding the proposed frontier State wage index adjustment would result in no change to the cumulative −2.0 percent decrease. Column 6 shows that adding the proposed changes in outlier and pass-though payments would result in an additional 0.4 percent increase in payment for CMHCs, for a total decrease of −1.6 percent. This reflects all proposed changes to CMHCs for CY 2015.

(4) Estimated Effect of Proposed OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary share of payment would increase for services for which the OPPS payments would rise and would decrease for services for which the OPPS payments would fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this proposed rule. In all cases, the statute limits beneficiary liability for copayment for a procedure to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be 20.1 percent for all services paid under the OPPS in CY 2015. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including proposed recalibration of the APC relative payment weights, proposed change in the portion of OPPS payments dedicated to pass-through payments, and the CY 2015 comprehensive APC policy discussed in section II.A.2.e. of this proposed rule.

(5) Estimated Effects of Proposed OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XII. of this proposed rule. No types of providers or suppliers other than hospitals, CMHCs and ASCs would be affected by the proposed changes in this proposed rule.

(6) Estimated Effects of Proposed OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be $800 million in additional program payments for OPPS services furnished in CY 2015. The effect on the Medicaid program is expected to be limited to increased copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We refer readers to our discussion of the impact on beneficiaries in section XXI.A. of this proposed rule.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing to make and the reasons for our selected alternatives are discussed throughout this proposed rule.

• Alternatives Considered for the Establishment of Comprehensive APCs

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910 and 75184 through 75185) for a discussion of our policy to establish comprehensive APCs for CY 2015 and the alternatives we considered. We note that we published tables in that final rule with comment period to demonstrate how this policy would have been implemented in CY 2014, and stated that we would be considering any additional public comments we receive when we update the policy for CY 2015 to account for changes that may occur in the CY 2013 claims data.

b. Estimated Effects of CY 2015 ASC Payment System Proposed Policies

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XII. of this proposed rule, we are proposing to set the CY 2015 ASC relative payment weights by scaling the proposed CY 2015 OPPS relative payment weights by the proposed ASC scaler of 0.9142. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 53 and 54 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which currently is the CPI–U) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2015 payment determinations will be based on the application of a 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U. We calculated the proposed CY 2015 ASC conversion factor by adjusting the CY 2014 ASC conversion factor by 0.9983 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2014 and CY 2015 and by applying the proposed CY 2015 MFP-adjusted CPI–U update factor of 1.2 percent (projected CPI–U update of 1.7 percent minus a projected productivity adjustment of 0.5 percent). The proposed CY 2015 ASC conversion factor is $43.918.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2015 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2013 and CY 2015 with precision. We believe that the net effect on Medicare expenditures resulting from the proposed CY 2015 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of ASC Payment System Proposed Policies on ASCs

Some ASCs are multispecialty facilities that perform the gamut of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the proposed update to the CY 2015 payments would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are

Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 2015 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2013 claims data. Table 53 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2014 payments to estimated CY 2015 payments and Table 54 shows a comparison of estimated CY 2014 payments to estimated CY 2015 payments for procedures that we estimate would receive the most Medicare payment in CY 2014.

Table 53 shows the estimated effects on aggregate Medicare payments under the ASC payment system by surgical specialty or ancillary items and services group. We have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 53.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2014 ASC Payments were calculated using CY 2013 ASC utilization (the most recent full year of ASC utilization) and CY 2014 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2014 ASC payments.
- Column 3—Estimated CY 2015 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that are attributable to proposed updates to ASC payment rates for CY 2015 compared to CY 2014.

As seen in Table 53, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC rates for CY 2015 would result in a 2-percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, a 6-percent increase in aggregate payment amounts for digestive system procedures, a 1-percent increase in aggregate payment amounts for nervous system procedures, a 2-percent increase in aggregate payment amounts for musculoskeletal system procedures, and a 3-percent increase in aggregate payment amounts for genitourinary system procedures and integumentary system procedures.

An estimated increase in aggregate payment for the specialty group does not mean that all procedures in the group would experience increased payment rates. For example, the estimated increase for CY 2015 for digestive system procedures is likely due to an increase in the ASC payment weight for some of the high volume procedures, such as CPT code 43239 (Upper GI endoscopy biopsy) where estimated payment would increase by 9 percent for CY 2015.

Also displayed in Table 53 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services would not change for CY 2015.

TABLE 53—ESTIMATED IMPACT OF THE PROPOSED CY 2015 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2015 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group	Estimated CY 2014 ASC payments (in millions)	Estimated CY 2015 percent change
(1)	(2)	(3)
Total	$3,819	1
Eye and ocular adnexa	1,556	−2
Digestive system	780	6
Nervous system	572	1
Musculoskeletal system	474	2
Genitourinary system	167	3
Integumentary system	137	3
Respiratory system	54	1
Cardiovascular system	35	−3
Ancillary items and services	24	0
Auditory system	14	0
Hematologic & lymphatic systems	6	12

Table 54 below shows the estimated impact of the proposed updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2015. The table displays 30 of the procedures receiving the greatest estimated CY 2014 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2014 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2014 ASC Payments were calculated using CY 2013 ASC utilization (the most recent full year of ASC utilization) and the CY 2014 ASC payment rates. The estimated CY 2014 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2015 Percent Change reflects the percent differences between the estimated ASC

payment for CY 2014 and the estimated payment for CY 2015 based on the proposed update.

TABLE 54—ESTIMATED IMPACT OF THE PROPOSED CY 2015 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code *	Short descriptor	Estimated CY 2014 ASC payments (in millions)	Estimated CY 2015 percent change
(1)	(2)	(3)	(4)
66984	Cataract surg w/iol, 1 stage	$1,132	−2
43239	Upper GI endoscopy, biopsy	170	9
45380	Colonoscopy and biopsy	168	6
45385	Lesion removal colonoscopy	107	6
66982	Cataract surgery, complex	93	−2
64483	Inj foramen epidural l/s	90	0
62311	Inject spine l/s (cd)	79	0
45378	Diagnostic colonoscopy	72	6
66821	After cataract laser surgery	63	2
64493	Inj paravert f jnt l/s 1 lev	47	0
64635	Destroy lumb/sac facet jnt	45	−3
G0105	Colorectal scrn; hi risk ind	45	0
63650	Implant neuroelectrodes	41	5
G0121	Colon ca scrn not hi rsk ind	41	0
64590	Insrt/redo pn/gastr stimul	39	−4
15823	Revision of upper eyelid	35	1
63685	Insrt/redo spine n generator	35	27
29827	Arthroscop rotator cuff repr	34	1
64721	Carpal tunnel surgery	32	−1
29881	Knee arthroscopy/surgery	30	−1
29824	Shoulder arthroscopy/surgery	28	1
29880	Knee arthroscopy/surgery	25	−1
43235	Uppr gi endoscopy diagnosis	23	9
62310	Inject spine c/t	23	0
29823	Shoulder arthroscopy/surgery	22	1
52000	Cystoscopy	22	1
G0260	Inj for sacroiliac jt anesth	21	0
45384	Lesion remove colonoscopy	21	6
67042	Vit for macular hole	21	−1
26055	Incise finger tendon sheath	20	−1

(3) Estimated Effects of ASC Payment System Proposed Policies on Beneficiaries

We estimate that the proposed CY 2015 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures that we are adding to the ASC list of covered surgical procedures and for those that we are proposing to designate as office-based for CY 2015. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services). Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. However, for those additional procedures that we are proposing to designate as office-based in CY 2015, the beneficiary coinsurance amount under the ASC payment system generally would be no greater than the beneficiary coinsurance under the MPFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

(4) Alternative ASC Payment Policies Considered

Alternatives to the minor changes that we are proposing to make to the ASC payment system and the reasons that we have chosen specific options are discussed throughout this proposed rule. There are no proposed major changes to ASC policies for CY 2015.

c. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget Web site at: *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), we have prepared two accounting statements to illustrate the impacts of this proposed rule. The first accounting statement, Table 55 (below), illustrates the classification of expenditures for the CY 2015 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2015

OPD fee schedule increase, based on the 2014 Trustee's Report. The second accounting statement, Table 56 (below), illustrates the classification of expenditures associated with the 1.2 percent proposed CY 2015 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the 2014 Trustee's Report. Lastly, the tables classify most estimated impacts as transfers.

TABLE 55—ACCOUNTING STATEMENT: CY 2015 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2014 TO CY 2015 ASSOCIATED WITH THE PROPOSED CY 2015 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$800 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS.
Total	$800 million.

TABLE 56—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2014 TO CY 2015 AS A RESULT OF THE PROPOSED CY 2015 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$36 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	$36 million.

d. Effects of Proposed Requirements for the Hospital OQR Program

In section XIII. of this proposed rule, we are proposing to adopt policies affecting the Hospital OQR Program.

Of 3,325 hospitals that met eligibility requirements for the CY 2014 payment determination, we determined that 88 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Most of these hospitals (70 of the 88) chose not to participate in the Hospital OQR Program for the CY 2014 payment determination. We estimate that approximately 90 hospitals will not receive the full OPD fee schedule increase factor for the CY 2017 payment determination and subsequent years.

In sections XIII.E. and XIII.C.3.of this proposed rule, for the CY 2017 payment determination and subsequent years, we are proposing to add one claims-based quality measure and to remove three measures from the Hospital OQR Program. In sections XIII.D.3.b. and c. of this proposed rule we are proposing to remove one measure from the CY 2016 payment determination measure set and to change that measure from required to voluntary for the CY 2017 payment determination and subsequent years. Hospitals would not be subject to a payment reduction with respect to this measure for the CY 2016 payment determination or during the period of voluntary reporting.

Because the measure we are proposing to add for the CY 2017 payment determination and subsequent years is claims-based, it will not require additional burden from data reporting or other action on the part of the hospitals. Therefore, we do not anticipate that this measure will cause any additional facilities to fail the Hospital OQR Program requirements. We anticipate a reduction in burden of approximately 862,077 hours or $25.9 million across participating hospitals from the three measures we are proposing to remove and the one measure we are proposing to make voluntary as further detailed in sections XIII.C.3. and XIII.D.3.c. of this proposed rule, respectively, and the information collection requirements in section XIX.C.1. of this proposed rule.

The validation requirements for the CY 2017 payment determination and subsequent years would result in medical record documentation of approximately 6,000 cases per quarter (up to 12 cases per quarter for 500 hospitals) submitted to the designated CMS contractor. In section XIII.H.3.e. of this proposed rule, we are proposing to allow hospitals to submit medical record documentation for validation using either of two methods: (1) Through paper medical records; or (2) by securely transmitting electronic versions of medical information by either (a) downloading or copying the digital image of the patient chart onto CD, DVD, or flash drive and shipping the electronic media following instructions specified on the QualityNet Web site; or (b) securely submitting digital images (PDFs) of patient charts using a Secure File Transfer Portal on the QualityNet Web site.

As stated previously (76 FR 74577), we would pay for the cost of sending paper medical record documentation to the designated CMS contractor at the rate of 12 cents per page for copying and approximately $1.00 per case for postage. For both new proposed electronic methods, we are proposing in the information collection requirements section of this proposed rule to reimburse hospitals for sending medical records electronically at a rate of $3.00 per patient chart.

As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75192), we have found that an outpatient medical chart is generally up to 10 pages. However, because we do not yet know how many hospitals will choose to submit data electronically or through paper, we cannot estimate the total cost of expenditures and are unable to estimate the number of hospitals that would fail the validation documentation submission requirement for the CY 2017 payment determination. Because we would pay for the data collection effort though, we believe that a requirement for medical record documentation for up to 12 cases per quarter for up to 500 hospitals for CY 2015 represents a minimal burden to Hospital OQR Program participating hospitals.

e. Effects of CY 2015 Proposed Policies for the ASCQR Program

In section XIV. of this proposed rule, we are proposing to adopt policies affecting the ASCQR Program. Of 5,300 ASCs that met eligibility requirements, we determined that 116 ASCs did not meet the requirements to receive the full annual payment update for CY 2014.

In section XIV.B.5. of this proposed rule, for the CY 2017 payment

determination and subsequent years, we are proposing to add one claims-based quality measure. The measure we are proposing for CY 2017 and subsequent years is claims-based and would not require additional data reporting or other action by ASCs. Therefore, we do not anticipate that this measure would cause any additional ASCs to fail to meet the ASCQR Program requirements. We present the time and burdens associated with our policies and proposals in section XIX.C.2. of this proposed rule.

In section XIV.E.3.b. of this proposed rule, we note a 3-month delay in data collection for two measures for the CY 2016 payment determination. We do not believe that this 3-month delay in data collection would significantly affect the number of ASCs that meet the ASCQR Program requirements.

In section XIV.E.3.c. of this proposed rule, we are proposing that one measure which was to be first included in the CY 2016 payment determination, would not be included in the CY 2016 measure set and that the measure would be voluntary for the CY 2017 payment determination and subsequent years. ASCs would not be subject to a payment reduction for the CY 2016 payment determination, nor would ASCs be subject to a payment reduction for the CY 2017 payment determination and subsequent years for failing to report this measure. Because this measure was not included in the CY 2014 payment determination and has not yet affected any payment determination, we do not believe that there will be an impact on the number of ASCs that meet the ASCQR Program requirements from our proposals not to include this measure in the measure set for the CY 2016 payment determination and to make this measure voluntary for the CY 2017 payment determination and subsequent years.

We do not believe that the other measures we previously adopted would cause any additional ASCs to fail to meet the ASCQR Program requirements. (We refer readers to the CY 2014 OPPS/ASC final rule with comment period for a list of these measures (78 FR 75130).

Further, we do not believe that any of the proposals in this proposed rule would significantly affect the number of ASCs that do not receive a full annual payment update for the CY 2017 payment determination. We are unable to estimate the number of ASCs that would not receive the full annual payment update based on the CY 2015 and CY 2016 payment determinations (78 FR 75192). For this reason, using the CY 2014 payment determination numbers as a baseline, we estimate that approximately 116 ASCs would not receive the full annual payment update in CY 2017 due to failure to meet the ASCQR Program requirements.

f. Effects of Proposed Changes to the Rural Provider and Hospital Ownership Exceptions to the Physician Self-Referral Law

Section 6001(a) of the Affordable Care Act amended the rural provider and hospital ownership exceptions to the physician self-referral law (sections 1877(d)(2) and (d)(3) of the Act, respectively) to impose additional restrictions on physician ownership or investment in hospitals. The amended rural provider and hospital ownership exceptions provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). We issued regulations addressing the prohibition against facility expansion in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72240).

Section 6001(a)(3) of the Affordable Care Act added section 1877(i)(3)(A)(i) of the Act to set forth that the Secretary shall establish and implement an exception process to the prohibition on expansion of facility capacity. We issued regulations that govern the expansion exception process in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74517) at 42 CFR 411.362(c). The regulations addressing the expansion exception process were issued by January 1, 2012, and the process was implemented on February 1, 2012.

As required by the statute, the expansion exception process provides that hospitals that qualify as an ''applicable hospital'' or a ''high Medicaid facility'' may request an exception to the prohibition on facility expansion. The existing expansion exception process requires the use of filed Medicare cost report data from the Healthcare Cost Report Information System (HCRIS) for hospitals to demonstrate that they satisfy the relevant eligibility criteria set forth in § 411.362(c)(2) for applicable hospitals and § 411.362(c)(3) for high Medicaid facilities (76 FR 42350 through 42352). In section XV. of this proposed rule, we discuss our proposal to permit hospitals also to use internal or external data sources, as defined in the proposal, to demonstrate satisfaction of the eligibility criteria. Under our proposal, we would continue to require each hospital seeking to qualify for an expansion exception to access and utilize data for its estimations or determinations to demonstrate that the hospital meets the relevant criteria and to provide a detailed explanation regarding whether and how it satisfies each of the relevant criteria. We believe the impact of our proposed modification on affected hospitals would be minimal, given that the use of data from an internal or external source is voluntary.

Our proposal would require each requesting hospital also to provide actual notification that it is requesting an expansion exception directly to hospitals whose data are part of the comparisons set forth in §§ 411.362(c)(2)(ii) and (c)(3)(ii) of the regulations, in addition to performing the other methods of notification specified in our existing regulations. We believe the impact of this proposed additional requirement on physician-owned hospitals would be minimal.

We believe that our proposals would affect a relatively small number of physician-owned hospitals. We estimate that there are approximately 265 physician-owned hospitals in the country. Since the process was implemented in February 2012, we have received only four requests, only one of which has been considered sufficiently complete to continue with publication in the **Federal Register**, under the current regulations. We anticipate receiving a similar number of requests each year. We do not believe that we can use the four requests to estimate accurately the potential increase in operating rooms, procedure rooms, and beds pursuant to approved expansion exception requests, and we are not aware of any data that may indicate such an increase. At this time, we also have no data or projections that may help estimate the number of physicians that would be affected by these proposals as a result of their ownership interests in hospitals.

We believe that beneficiaries may be positively impacted by our proposals. Specifically, an increase in operating rooms, procedure rooms, and beds may augment the volume or nature of services offered by physician-owned hospitals. An expansion in the number of hospital beds may also permit additional inpatient admissions and overnight stays. Increased operating rooms, procedure rooms, and beds may result in improved access to health care facilities and services. We believe that our proposals are necessary to conform our regulations to the amendments to section 1877 of the Act.

We are soliciting public comments on each of the issues outlined above that contain estimates of the costs and benefits of the proposed rule. We are specifically soliciting comments on the potential impact on State governments, given that we are proposing to define external data sources as data sources generated, maintained, or under the control of a State Medicaid agency.

g. Effects of Proposed Policies Related to CMS-Identified Overpayments Associated With Payment Data Submitted by Medicare Advantage (MA) Organizations and Medicare Part D Sponsors

In section XVII. of this proposed rule, we discuss our proposals to set forth in regulations a formal process, including appeals processes, that allows us to recoup overpayments in the limited set of circumstances where CMS makes a determination that an overpayment to an MA organization or Part D sponsor occurred because the organization or sponsor submitted erroneous data to CMS. It is difficult to predict how many times CMS would annually determine an overpayment due to erroneous data submitted to CMS by the MA organization or Part D sponsor and that, therefore, would be subject to the proposed offset and appeals regulations. However, we predict that it would be highly unlikely to exceed 10 cases a year and would probably be fewer. Further, electing to appeal a CMS overpayment determination under the proposed regulations is completely at the discretion of the MA organization or Part D sponsor. The MA organization or Part D sponsor may agree that the data require correction and resubmit the data; MA organizations and Part D sponsors that receive notification of an overpayment are under no obligation to initiate the appeal process. If the MA organization or Part D sponsor chooses not to appeal, there are no costs or burden associated with the appeal. If the MA organization or Part D sponsor chooses to appeal the overpayment determination, there would be costs associated with preparing the appeal request.

We are proposing three levels of appeal review (reconsideration, informal hearing, and Administrator review), each of which the MA organization or Part D sponsor would have to request. Once the appeal has been filed, however; there will be little or no cost experienced by the MA organization or Part D sponsor because the appeal process is on the record and would not involve oral testimony. The extent to which there would be costs associated with preparing the appeal request is subject to preference and choice. We estimate that it would take a plan 5 hours to prepare and file a reconsideration request. In terms of cost, it has been our experience that most appeals have been prepared by high-level officials of the plan or lawyers. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2012, the mean hourly wage for the category of ''Lawyers''—which we believe, considering the variety of officials who have submitted appeals, is the most appropriate category—is $62.93. Multiplying this figure by 50 hours (10 submissions × 5 hours) results in a projected annual cost burden of $3,147. We estimate the preparation and filing of a request for a hearing, or for Administrator's review would take 2 hours, at most, because the MA organization or Part D sponsor cannot submit new evidence. The hearing officer or Administrator is limited to a review of the record. Multiplying this figure by 40 hours (10 submissions × 4 hours) results in a projected annual cost burden of $2,517. It is estimated that if the costs of benefits and overhead are included, the total annual costs for requests at the three levels would be approximately $11,000.

B. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $35.5 million or less in any single year. Most ASCs and most CMHCs are considered small businesses with total revenues of $14 million or less in any single year. We estimate that this proposed rule may have a significant impact on approximately 2,007 hospitals with voluntary ownership. For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards*.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule may have a significant impact on approximately 709 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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. That threshold level is currently approximately $141 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are proposing to make in this proposed rule would affect all classes of hospitals paid under the OPPS and would affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2015. Table 52 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 2.2 percent increase in payments for all services paid under the OPPS in CY 2015, after considering all of the proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed wage index changes, including the proposed frontier State wage index adjustment, estimated payment for outliers, and proposed changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains and others would experience modest losses in OPPS payments in CY 2015.

The proposed updates to the ASC payment system for CY 2015 would affect each of the approximately 5,300 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under

the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 53 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI–U update factor of 1.2 percent for CY 2015.

XXII. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they would not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 52 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.2 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance, organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health professions, Medicare.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR Chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATION ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 2. Section 411.351 is amended by adding the definitions ''External data source'' and ''Internal data source'' in alphabetical order to read as follows:

§ 411.351 Definitions.

* * * * *

External data source means a data source that—

(1) Is generated, maintained, or under the control of a State Medicaid agency;

(2) Is reliable and transparent;

(3) Maintains data that, for purposes of the process described in § 411.362(c), are readily available and accessible to the requesting hospital, comparison hospitals, and CMS; and

(4) Maintains or generates data that, for purposes of the process described in § 411.362(c), are accurate, complete, and objectively verifiable.

* * * * *

Internal data source means a data source other than the Healthcare Cost Report Information System that—

(1) Is generated, maintained, or under the control of the Department;

(2) Is reliable and transparent;

(3) Maintains data that, for purposes of the process described in § 411.362(c), are readily available and accessible to the requesting hospital, comparison hospitals, and CMS; and

(4) Maintains or generates data that, for purposes of the process described in § 411.362(c), are accurate, complete, and objectively verifiable.

* * * * *

■ 3. Section 411.362 is amended by revising paragraphs (c)(2)(ii), (c)(2)(iv), (c)(2)(v), (c)(3)(ii), and (c)(5) to read as follows:

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

* * * * *

(c) * * *

(2) * * *

(ii) *Medicaid inpatient admissions.* Has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located during the most recent fiscal year for which data are available as of the date that the hospital submits its request. A hospital must use only filed Medicare hospital cost report data, data from an internal data source (as defined at § 411.351), and/or data from an external data source (as defined at § 411.351) to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located:

* * * * *

(iv) *Average bed capacity.* Is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which data are available as of the date that the hospital submits its request. A hospital must use only filed Medicare hospital cost report data, data from an internal data source (as defined at § 411.351), and/or data from an external data source (as defined at § 411.351) to determine the average bed capacity in the State in which the hospital is located and the national average bed capacity.

(v) *Average bed occupancy.* Has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which data are available as of the date that the hospital submits its request. A hospital must use only filed Medicare hospital cost report data, data from an internal data source (as defined at § 411.351), and/or data from an external data source (as defined at § 411.351) to determine its average bed occupancy rate and the average bed

occupancy rate for the State in which the hospital is located.

(3) * * *

(ii) *Medicaid inpatient admissions.* With respect to each of the 3 most recent fiscal years for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located. A hospital must use only filed Medicare hospital cost report data, data from an internal data source (as defined at § 411.351), and/or data from an external data source (as defined at § 411.351) to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

* * * * *

(5) *Community input and timing of complete request.* Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public Web site for the hospital that it is requesting an exception and must also provide actual notification that it is requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2)(ii) and (c)(3)(ii) of this section. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the **Federal Register**. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS. If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

(i) If only filed Medicare hospital cost report data are used in the hospital's request, the written comments, and the hospital's rebuttal statement—

(A) A request will be deemed complete at the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete at the end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(ii) If data from an internal data source or external data source are used in the hospital's request, the written comments, or the hospital's rebuttal statement—

(A) A request will be deemed complete no later than 180 days after the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete no later than 180 days after the end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 4. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), and sec. 124 of Public Law 106–113 (113 Stat.1501A–332).

§ 412.3 [Amended]

■ 5. Section 412.3 is amended by—

■ a. Removing paragraph (c).

■ b. Redesignating paragraphs (d) and (e) as paragraphs (c) and (d), respectively.

■ c. In newly redesignated paragraph (d)(1), removing the cross-reference ''paragraph (e)(2)'' and adding in its place the cross-reference ''paragraph (d)(2)''.

PART 416—AMBULATORY SURGICAL SERVICES

■ 6. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 7. Section 416.164 is amended by revising paragraphs (a)(11) and (b)(5) to read as follows:

§ 416.164 Scope of ASC services.

(a) * * *

(11) Radiology services for which separate payment is not allowed under the OPPS and other diagnostic tests or interpretive services that are integral to a surgical procedure, except certain diagnostic tests for which separate payment is allowed under the OPPS;

* * * * *

(b) * * *

(5) Certain radiology services and certain diagnostic tests for which separate payment is allowed under the OPPS.

* * * * *

■ 8. Section 416.171 is amended by revising paragraphs (b)(1) and (2) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services and certain diagnostic tests as provided in § 416.164(b)(5);

(2) The device portion of device-intensive procedures, which are procedures assigned to an APC with a device cost greater than 40 percent of the APC costs when calculated according to the standard OPPS APC ratesetting methodology.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 9. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

■ 10. Section 419.2 is amended by revising paragraphs (b)(7) and (16) to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) * * *

(7) Ancillary services;

* * * * *

(16) Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals);

* * * * *

■ 11. Section 419.22 is amended by revising paragraph (j) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(j) Except as provided in § 419.2(b)(11), prosthetic devices and orthotic devices.

* * * * *

■ 12. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*6*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*6*) For calendar year 2015, a multifactor productivity adjustment (as determined by CMS) and 0.2 percentage point.

* * * * *

§ 419.46 [Amended]

■ 13. Section 419.46 is amended by—

■ a. In paragraph (c)(1), removing the phrase ''section 1833(17)(C)'' and adding in its place the phrase ''section 1833(t)(17)(C)''.

■ b. In paragraph (d) introductory text and paragraph (d)(1), removing the term ''waiver'' and adding in its place the term ''exception'' each time it apppears.

■ c. In paragraph (d)(2), removing the term ''waivers'' and adding in its place the term ''exceptions''.

■ d. In paragraph (e) introductory text, removing the phrase ''section 1833(17)(C)'' and adding in its place the phrase ''section 1833(t)(17)(C)''.

■ 14. Section 419.64 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 419.64 Transitional pass-through payments: Drugs and biologicals.

* * * * *

(a) * * *

(4) * * *

(iv) A biological that is not a skin substitute or similar product that aids wound healing, unless pass-through payment for a skin substitute as a biological is made on or before January 1, 2015.

* * * * *

■ 15. Section 419.66 is amended by revising paragraph (b)(3) and removing paragraph (b)(4)(iii).

The revision reads as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(b) * * *

(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.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 16. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 17. Section 422.330 is added to subpart G to read as follows:

§ 422.330 CMS-identified overpayments associated with payment data submitted by MA organizations.

(a) *Definitions.* For purposes of this section—

Payment data means data controlled and submitted by an MA organization to CMS and used for payment purposes, including enrollment data and data submitted under § 422.310.

Applicable reconciliation date occurs on the date of the annual final deadline for risk adjustment data submission described at § 422.310(g)(2)(ii).

(b) *Request to correct payment data.* If CMS identifies an error in payment data other than an error identified through the process described in § 422.311, and the payment error identified affects payments for any of the 6 most recently completed payment years, CMS may send a data correction notice to the MA organization requesting that the MA organization correct the payment data. The notice will include or make reference to the specific payment data that need to be corrected, the reason why CMS believes that the payment data are erroneous, and the timeframe for correcting the payment data.

(c) *Payment offset.* If the MA organization fails to submit the corrected payment data within the timeframe as requested in accordance with paragraph (b) of this section, CMS will conduct a payment offset against payments made to the MA organization. CMS will calculate the payment offset amount using a payment algorithm that applies the payment rules for the applicable year.

(d) *Payment offset notification.* CMS will issue a payment offset notice to the MA organization that includes the following:

(1) The dollar amount of the offset from plan payments.

(2) An explanation of how the erroneous data were identified and used to calculate the payment offset amount.

(3) An explanation that, if the MA organization disagrees with the payment offset, it may request an appeal within 30 days of issuance of the payment offset notification.

(e) *Appeals process.* If an MA organization does not agree with the payment offset described in paragraph (c) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* An MA organization may request reconsideration of the payment offset described in paragraph (c) of this section, according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 30 days from the date that CMS issued the payment offset notice to the MA organization.

(ii) *Content of request.* The written request for reconsideration must specify the findings or issues with which the MA organization disagrees and the reasons for its disagreement. As part of its request for reconsideration, the MA organization may include any additional documentary evidence in support of its position. Any additional evidence must be submitted with the request for reconsideration. Additional information submitted after this time will be rejected as untimely.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the underlying data that were used to determine the amount of the payment offset and any additional documentary evidence timely submitted by the MA organization.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the MA organization of its decision on the reconsideration request.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (e)(2) of this section.

(2) *Informal hearing.* An MA organization dissatisfied with CMS' reconsideration decision made under paragraph (e)(1) of this section is entitled to an informal hearing as provided for under paragraphs (e)(2)(i) through (v) of this section.

(i) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with CMS within 30 days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the MA organization disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(B) The informal hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not timely presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before the CMS reconsideration official when CMS made its reconsideration determination.

(C) The CMS hearing officer will review the proceeding before the CMS reconsideration official on the record made before the CMS reconsideration official using the clearly erroneous standard of review.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the MA organization explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (e)(3) of this section.

(3) *Review by the Administrator.* The Administrator review will be conducted in the following manner:

(i) An MA organization that has received a hearing officer's decision may request review by the Administrator within 30 days of the date of issuance of the hearing officer's decision under paragraph (e)(2)(iv) of this section. The MA organization may submit written arguments to the Administrator for review.

(ii) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (e)(3)(iii) of this section or to decline to review the hearing officer's decision.

(iii) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iv) If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(v) The Administrator's determination is final and binding.

(f) *Matters subject to appeal and burden of proof.*

(1) The MA organization's appeal is limited to CMS' finding that the payment data submitted by the MA organization are erroneous.

(2) The MA organization bears the burden of proof by a preponderance of the evidence in demonstrating that CMS' finding that the payment data were erroneous was incorrect or otherwise inconsistent with applicable program requirements.

(g) *Applicability of appeals process.* The appeals process under paragraph (e) of this section applies only to payment offsets under paragraph (c) of this section.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 18. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 19. Section 423.352 is added to read as follows:

§ 423.352 CMS-identified overpayments associated with payment data submitted by Part D sponsors.

(a) *Definitions.* For purposes of this section—

Applicable reconciliation date occurs on the later of either the annual deadline for submitting—

(1) Prescription drug event (PDE) data for the annual Part D payment reconciliations referred to in § 423.343(c) and (d); or

(2) Direct and indirect remuneration data.

Payment data means data controlled and submitted by a Part D sponsor to CMS and used for payment purposes, including enrollment data and data submitted under §§ 423.329(b)(3), 423.336(c)(1), and 423.343, and data provided for purposes of supporting allowable reinsurance costs and allowable risk corridor costs as defined in § 423.308, including data submitted to CMS regarding direct and indirect remuneration.

(b) *Request to correct payment data.* If CMS identifies an error in payment data submitted by a Part D sponsor, and the payment error identified affects payments for any of the 6 most recently completed payment years, CMS may send a data correction notice to the Part D sponsor requesting that the Part D sponsor correct the payment data. The notice will include or make reference to the specific payment data that need to be corrected, the reason why CMS believes that the payment data are erroneous, and the timeframe for correcting the payment data.

(c) *Payment offset.* If the Part D sponsor fails to submit the corrected payment data within the timeframe as requested in accordance with paragraph (b) of this section, CMS will conduct a payment offset against payments made to the Part D sponsor. CMS will calculate the payment offset amount using a payment algorithm that applies the payment rules for the applicable year.

(d) *Payment offset notification.* CMS will issue a payment offset notice to the Part D sponsor that includes the following:

(1) The dollar amount of the offset from plan payments.

(2) An explanation of how the erroneous data were identified and used to calculate the payment offset amount.

(3) An explanation that, if the Part D sponsor disagrees with the payment offset, it may request an appeal within 30 days of issuance of the payment offset notification.

(e) *Appeals process.* If a Part D sponsor does not agree with the payment offset described in paragraph (c) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* A Part D sponsor may request reconsideration of the payment offset described in paragraph (c) of this section, according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 30 days from the date that CMS issued the payment offset notice to the Part D sponsor.

(ii) *Content of request.* The written request for reconsideration must specify the findings or issues with which the Part D sponsor disagrees and the reasons for its disagreement. As part of its request for reconsideration, the Part D sponsor may include any additional documentary evidence in support of its position. Any additional evidence must be submitted with the request for reconsideration. Additional information submitted after this time will be rejected as untimely.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the underlying data that were used to determine the amount of the payment offset and any additional documentary evidence timely submitted by the Part D sponsor.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the Part D sponsor of its decision on the reconsideration request.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (e)(2) of this section.

(2) *Informal hearing.* A Part D sponsor dissatisfied with CMS' reconsideration decision made under paragraph (e)(1) of this section is entitled to an informal hearing as provided for under paragraphs (e)(2)(i) through (v) of this section.

(i) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with CMS

within 30 days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(B) The informal hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not timely presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before the CMS reconsideration official when CMS made its reconsideration determination.

(C) The CMS hearing officer will review the proceeding before the CMS reconsideration official on the record made before the CMS reconsideration official using the clearly erroneous standard of review.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (e)(3) of this section.

(3) *Review by the Administrator.* The Administrator review will be conducted in the following manner:

(i) A Part D sponsor that has received a hearing officer's decision may request review by the Administrator within 30 days of the date of issuance of the hearing officer's decision under paragraph (e)(2)(iv) of this section. The Part D sponsor may submit written arguments to the Administrator for review.

(ii) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (e)(3)(iii) of this section or to decline to review the hearing officer's decision.

(iii) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iv) If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the Part D sponsor, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(v) The Administrator's determination is final and binding.

(f) *Matters subject to appeal and burden of proof.* (1) The Part D sponsor's appeal is limited to CMS' finding that the payment data submitted by the Part D sponsor are erroneous.

(2) The Part D sponsor bears the burden of proof by a preponderance of the evidence in demonstrating that CMS' finding that the payment data were erroneous was incorrect or otherwise inconsistent with applicable program requirements.

(g) *Applicability of appeals process.* The appeals process under paragraph (e) of this section applies only to payment offsets under paragraph (c) of this section.

PART 424—CONDITIONS FOR PAYMENT

■ 20. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 21. Section 424.13 is amended by—

■ a. Revising paragraph (a) introductory text.

■ b. Removing paragraph (a)(1).

■ c. Redesignating paragraphs (a)(2), (3), and (4) as paragraphs (a)(1), (2), and (3), respectively.

■ d. Revising newly redesignated paragraph (a)(1)(i).

■ e. Revising paragraph (b).

The revisions read as follows:

§ 424.13 Requirements for inpatient services of hospitals other than inpatient psychiatric facilities.

(a) *Content of certification and recertification.* Medicare Part A pays for inpatient hospital services (other than inpatient psychiatric facility services) for cases that are 20 inpatient days or more, or are outlier cases under subpart F of part 412 of this chapter, only if a physician certifies or recertifies the following:

* * * * *

(1) * * *

(i) Hospitalization of the patient for medical treatment or medically required diagnostic study; or

* * * * *

(b) *Timing of certification.* For outlier cases under subpart F of part 412 of this chapter, the certification must be signed and documented in the medical record and as specified in paragraphs (e) through (h) of this section. For all other cases, the certification must be signed and documented no later than 20 days into the hospital stay.

* * * * *

Dated: June 24, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 27, 2014.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2014–15939 Filed 7–3–14; 4:15 pm]

BILLING CODE 4120–01–P