DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 476

[CMS–1518–P]

RIN 0938–AQ24

Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates

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

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems and to implement certain statutory provisions contained in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act) and other legislation. These changes would be applicable to discharges occurring on or after October 1, 2011. We also are setting forth the proposed update to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits. The proposed updated rate-of-increase limits would be effective for cost reporting periods beginning on or after October 1, 2011.

We are proposing to update the payment policy and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and implement certain statutory changes made by the Affordable Care Act. These changes would be applicable to discharges occurring on or after October 1, 2011.

DATES: *Comment Period:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EDT on June 20, 2011.

ADDRESSES: When commenting, please refer to file code CMS–1518–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation at *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" and enter the file code CMS–1518–P to submit comments on this proposed rule.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1518–P, P.O. Box 8011, 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 (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1518–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 (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the HHH 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. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call 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, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Tzvi Hefter, (410) 786–4487, and Ing-Jye Cheng, (410) 786–4548, Operating Prospective Payment, MS–DRGs, Hospital Acquired Conditions (HAC), Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH), and Postacute Care Transfer Issues.

Michele Hudson, (410) 786–4487, and Judith Richter, (410) 786–2590, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Bridget Dickensheets, (410) 786–8670, Rebasing and Revising of the Market Basket for LTCHs Issues.

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

James Poyer, (410) 786–2261, Inpatient Quality Reporting—Program Administration, Validation, and Reconsideration Issues.

Shaheen Halim, (410) 786–0641, Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

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

Mary Pratt, (410) 786–6867, LTCH Quality Data Reporting Issues.

Kim Spaulding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions at 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 a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Tables Available Only Through the Internet on the CMS Web Site

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to this proposed rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of the IPPS tables and LTCH PPS tables will no longer be published as part of the annual IPPS/LTCH PPS proposed and final rules. Instead, these tables will be available only through the Internet. The IPPS tables for this proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp.* Click on the link on the left side of the screen titled, "FY 2012 IPPS Proposed Rule Home Page" or "Acute Inpatient—Files for Download". The LTCH PPS tables for this FY 2012 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/LongTermCareHospitalPPS/LTCHPPSRN/list.asp* under the list item for Regulation Number CMS–1518–P. For complete details on the availability of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this proposed rule. Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Nisha Bhat at (410) 786–4487.

Acronyms

3M 3M Health Information System
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
AHA American Hospital Association
AHIC American Health Information Community
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
ALOS Average length of stay
ALTHA Acute Long Term Hospital Association
AMA American Medical Association
AMGA American Medical Group Association
AOA American Osteopathic Association
APR DRG All Patient Refined Diagnosis Related Group System
ARRA American Recovery and Reinvestment Act of 2009, Public Law 111–5
ASC Ambulatory surgical center
ASCA Administrative Simplification Compliance Act of 2002, Public Law 107–105
ASITN American Society of Interventional and Therapeutic Neuroradiology
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CAH Critical access hospital
CARE [Medicare] Continuity Assessment Record & Evaluation [Instrument]
CART CMS Abstraction & Reporting Tool
CBSAs Core-based statistical areas
CC Complication or comorbidity
CCR Cost-to-charge ratio
CDAC [Medicare] Clinical Data Abstraction Center
CDAD *Clostridium difficile*-associated disease
CIPI Capital input price index
CMI Case-mix index
CMS Centers for Medicare & Medicaid Services
CMSA Consolidated Metropolitan Statistical Area
COBRA Consolidated Omnibus Reconciliation Act of 1985, Public Law 99–272
COLA Cost-of-living adjustment
CoP [Hospital] condition of participation
CPI Consumer price index
CRNA Certified Registered Nurse Anesthetist
CY Calendar year
DPP Disproportionate patient percentage
DRA Deficit Reduction Act of 2005, Public Law 109–171
DRG Diagnosis-related group
DSH Disproportionate share hospital
ECI Employment cost index
EDB [Medicare] Enrollment Database
EHR Electronic health record
EMR Electronic medical record
FAH Federation of Hospitals
FDA Food and Drug Administration
FFY Federal fiscal year
FQHC Federally qualified health center
FTE Full-time equivalent
FY Fiscal year
GAAP Generally Accepted Accounting Principles
GAF Geographic Adjustment Factor
GME Graduate medical education
HACs Hospital-acquired conditions
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCFA Health Care Financing Administration
HCO High-cost outlier
HCRIS Hospital Cost Report Information System
HHA Home health agency
HHS Department of Health and Human Services
HICAN Health Insurance Claims Account Number
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HIPC Health Information Policy Council
HIS Health information system
HIT Health information technology
HMO Health maintenance organization
HPMP Hospital Payment Monitoring Program
HSA Health savings account
HSCRC [Maryland] Health Services Cost Review Commission
HSRV Hospital-specific relative value
HSRVcc Hospital-specific relative value cost center
HQA Hospital Quality Alliance
HQI Hospital Quality Initiative
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
ICD–10–PCS International Classification of Diseases, Tenth Revision, Procedure Coding System
ICR Information collection requirement
IGI IHS Global Insight, Inc.
IHS Indian Health Service
IME Indirect medical education
I–O Input-Output
IOM Institute of Medicine
IPF Inpatient psychiatric facility
IPPS [Acute care hospital] inpatient prospective payment system
IRF Inpatient rehabilitation facility
IQR Inpatient Quality Reporting
LAMCs Large area metropolitan counties
LOS Length of stay
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
MA Medicare Advantage
MAC Medicare Administrative Contractor
MCC Major complication or comorbidity
MCE Medicare Code Editor
MCO Managed care organization
MCV Major cardiovascular condition
MDC Major diagnostic category
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare Provider Analysis and Review File
MEI Medicare Economic Index
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275

MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MRHFP Medicare Rural Hospital Flexibility Program
MRSA Methicillin-resistant *Staphylococcus aureus*
MSA Metropolitan Statistical Area
MS–DRG Medicare severity diagnosis-related group
MS–LTC–DRG Medicare severity long-term care diagnosis-related group
NAICS North American Industrial Classification System
NALTH National Association of Long Term Hospitals
NCD National coverage determination
NCHS National Center for Health Statistics
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NECMA New England County Metropolitan Areas
NQF National Quality Forum
NTIS National Technical Information Service
NTTAA National Technology Transfer and Advancement Act of 1991 (Public Law 104–113)
NVHRI National Voluntary Hospital Reporting Initiative
OACT [CMS'] Office of the Actuary
OBRA 86 Omnibus Budget Reconciliation Act of 1996, Public Law 99–509
OES Occupational employment statistics
OIG Office of the Inspector General
OMB Executive Office of Management and Budget
OPM U.S. Office of Personnel Management
O.R. Operating room
OSCAR Online Survey Certification and Reporting [System]
PMSAs Primary metropolitan statistical areas
POA Present on admission
PPACA Patient Protection and Affordable Care Act, Public Law 111–148
PPI Producer price index
PPS Prospective payment system
PRM Provider Reimbursement Manual
ProPAC Prospective Payment Assessment Commission
PRRB Provider Reimbursement Review Board
PRTFs Psychiatric residential treatment facilities
PSF Provider-Specific File
PS&R Provider Statistical and Reimbursement (System)
QIG Quality Improvement Group, CMS
QIO Quality Improvement Organization
RCE Reasonable compensation equivalent
RHC Rural health clinic
RHQDAPU Reporting hospital quality data for annual payment update
RNHCI Religious nonmedical health care institution
RPL Rehabilitation psychiatric long-term care (hospital)
RRC Rural referral center
RTI Research Triangle Institute, International
RUCAs Rural-urban commuting area codes
RY Rate year
SAF Standard Analytic File
SCH Sole community hospital
SFY State fiscal year
SIC Standard Industrial Classification
SNF Skilled nursing facility
SOCs Standard occupational classifications
SOM State Operations Manual
SSO Short-stay outlier
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
TEP Technical expert panel
TMA TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110–90
UHDDS Uniform hospital discharge data set

Table of Contents

I. Background

A. Summary

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

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of hospital inpatient stays under a prospective payment system (PPS). Under these PPSs, Medicare payment

for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

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

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations.

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

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

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

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. Through and including FY 2006, a Medicare-dependent, small rural hospital (MDH) received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate is exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. As discussed below, for discharges occurring on or after October 1, 2007, but before October 1, 2012, an MDH will receive the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. SCHs are the sole source of care in their areas, and MDHs are a major source of care for Medicare beneficiaries in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). Both of these categories of hospitals are afforded this special payment protection in order to maintain access to services for beneficiaries.

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

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

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; and cancer hospitals. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for rehabilitation hospitals and units (referred to as inpatient rehabilitation facilities (IRFs)), LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are now included as part of the IPPS annual update document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, and RNHCIs continue to be paid solely under a reasonable cost-based system subject to a rate-of-increase ceiling on inpatient operating costs per discharge.

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

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

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123(a) and (c) of Public Law 106–113 and section 307(b)(1) of Public Law 106–554 (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on

reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006, all LTCHs are paid 100 percent of the Federal rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v)(1)(A) of the Act and existing regulations under 42 CFR parts 413 and 415.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

B. Provisions of the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) Applicable to FY 2012

The Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, made a number of changes that affect the IPPS and the LTCH PPS. (Pub. L. 111–148 and Pub. L. 111–152 are collectively referred to as the "Affordable Care Act.") A number of the provisions of the Affordable Care Act affect the updates to the IPPS and the LTCH PPS and providers and suppliers. The provisions of the Affordable Care Act that were applicable to the IPPS and the LTCH PPS for FYs 2010 and 2011 were implemented in the following documents:

On June 2, 2010, we issued in the **Federal Register** a notice (75 FR 31118) that contained the final wage indices, hospital reclassifications, payment rates, impacts, and other related tables, effective for the FY 2010 IPPS and the RY 2010 LTCH PPS, which were required by or directly resulted from implementation of provisions of the Affordable Care Act.

On August 16, 2010, we issued in the **Federal Register** a final rule (75 FR 50042) that implemented provisions of the Affordable Care Act applicable to the IPPS and LTCH/PPS for FY 2011.

In this proposed rule, we are proposing to implement the following provisions (or portions of the following provisions) of the Affordable Care Act that are applicable to the IPPS and LTCH PPS for FY 2012:

- Section 3001 of Public Law 111–148, which provides for establishment of a hospital value-based purchasing program and applicable measures for value-based incentive payments with respect to discharges occurring during FY 2013.
- Section 3004 of Public Law 111–148, which provides for the submission of quality data for LTCHs in order to receive the full annual update to the payment rates and the establishment of quality data measures.
- Section 3025 of Public Law 111–148, which provides for a hospital readmissions reduction program and related quality data reporting measures.
- Section 3124 of Public Law 111–148, which provides for extension of the Medicare-dependent, small rural hospital (MDH) program through FY 2012.
- Section 3401 of Public Law 111–148, which provides for the incorporation of productivity improvements into the market basket updates for IPPS hospitals and LTCHs.

In addition, we are proposing to continue in FY 2012 to implement the following provisions, which were initiated in FY 2011:

- Section 10324 of Public Law 111–148, which provided for a wage adjustment for hospitals located in frontier States.
- Sections 3401 and 10319 of Public Law 111–148 and section 1105 of Public Law 111–152, which revise certain market basket update percentages for IPPS and LTCH PPS payment rates for FY 2012.
- Sections 3125 and 10314 of Public Law 111–148, which provides for temporary percentage increases in payment adjustments to low-volume hospitals for discharges occurring in FY 2012.
- Section 1109 of Public Law 111–152, which provides for additional payments in FY 2012 for qualifying hospitals in the lowest quartile of per capita Medicare spending.

C. Major Contents of This Proposed Rule

In this proposed rule, we are setting forth proposed changes to the Medicare IPPS for operating costs and for capital-related costs of acute care hospitals in FY 2012. We also are setting forth proposed changes relating to payments for IME costs and payments to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis.

In addition, in this proposed rule, we are setting forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2012.

Below is a summary of the major changes that we are proposing to make:

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

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

- Proposed changes to MS–DRG classifications based on our yearly review.
- Proposed application of the documentation and coding adjustment for FY 2012 resulting from implementation of the MS–DRG system.
- A discussion of the Research Triangle International, Inc. (RTI) reports and recommendations relating to charge compression.
- Proposed recalibrations of the MS–DRG relative weights.
- Proposed changes to hospital-acquired conditions (HACs) and a listing and discussion of HACs, including infections, that would be subject to the statutorily required quality adjustment in MS–DRG payments for FY 2012.

We discussed the FY 2012 status of new technologies approved for add-on payments for FY 2011 and present our evaluation and analysis of the FY 2012 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting).

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

In section III. of the preamble to this proposed rule, we are proposing revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include the following:

- The proposed FY 2012 wage index update using wage data from cost reporting periods beginning in FY 2008.
- Analysis and implementation of the proposed FY 2012 occupational mix adjustment to the wage index for acute care hospitals, including discussion of the 2010 occupational mix survey.
- A proposal to change the reporting requirements for pension costs for the Medicare wage index.
- Proposed revisions to the wage index for acute care hospitals based on hospital redesignations and reclassifications.
- The proposed adjustment to the wage index for acute care hospitals for FY 2012 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- The timetable for reviewing and verifying the wage data used to compute the proposed FY 2012 hospital wage index.
- Determination of the labor-related share for the proposed FY 2012 wage index.

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

In section IV. of the preamble of this proposed rule, we discuss a number of the provisions of the regulations in 42 CFR parts 412, 413, and 476, including the following:

- The reporting of hospital quality data under the Hospital Inpatient Quality Reporting (IQR) Program as a condition for receiving the full annual payment update increase.
- The proposed implementation of the Hospital Value-Based Purchasing Program measures.
- The proposed establishment of hospital readmisssion measures for reporting of hospital quality data.
- The proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- The statutorily required IME adjustment factor for FY 2012.
- Proposed payment adjustment for low-volume hospitals.
- Proposal for counting hospice days in the formula for determining the payment adjustment for disproportionate share hospitals.
- Proposal for making additional payments for qualifying hospitals with lowest per enrollee Medicare spending for FY 2012.
- Proposal to clarify ESRD add-on payment requirements based on cost report requirements.
- Proposal relating to changes to the reporting requirements for pension costs for Medicare cost-finding purposes.
- Proposal to implement statutory change to the hospital payment update, including incorporation of a productivity adjustment.
- Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.
- Discussion of August 2010 interim final rule with comment period and further proposed changes relating to the 3-day payment window for payments for services provided to outpatients who are later admitted as inpatients.

4. Proposed FY 2012 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to this proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2012 and the proposed MS–DRG documentation and coding adjustment for FY 2012.

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

In section VI. of the preamble of this proposed rule, we discuss proposed changes to payments to certain excluded hospitals. In addition, we discuss proposed changes relating to payment for TEFRA services furnished under arrangements and payment for ambulance services furnished by CAH-owned and operated entities.

6. Proposed Changes to the LTCH PPS

In section VII. of the preamble of this proposed rule, we set forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2012, including the annual update of the MS–LTC–DRG classifications and relative weights for use under the LTCH PPS for FY 2012, the proposed documentation and coding adjustment under the LTCH PPS for FY 2012, and the proposed rebasing and revising of the market basket for LTCHs. In addition, we are setting forth proposals for implementing the quality data reporting program for LTCHs. We also are proposing to clarify two policies regarding the calculation of the average length of stay requirement for LTCHs, and proposing a policy to address a LTCH moratorium issue.

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

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2012 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We also are proposing to establish the threshold amounts for outlier cases. In addition, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2012 for certain hospitals excluded from the IPPS.

8. Determining Proposed Prospective Payment Rates for LTCHs

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2012 prospective standard Federal rate. We also are proposing to establish the proposed adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the fixed-loss amount, and the LTCH cost-to-charge ratios (CCRs) under the LTCH PPS.

9. Impact Analysis

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

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

In Appendix B of this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2012 for the following:

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

11. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 1 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2011 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and

capital-related costs under the IPPS, for hospitals and distinct part hospital units excluded from the IPPS. We address these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2011 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's Web site at: *http://www.medpac.gov.*

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

A. Background

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

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

B. MS–DRG Reclassifications

1. General

As discussed in the preamble to the FY 2008 IPPS final rule with comment period (72 FR 47138), we focused our efforts in FY 2008 on making significant reforms to the IPPS consistent with the recommendations made by MedPAC in its "Report to the Congress, Physician-Owned Specialty Hospitals" in March 2005. MedPAC recommended that the Secretary refine the entire DRG system by taking severity of illness into account and applying hospital-specific relative value (HSRV) weights to DRGs.[1] We began this reform process by adopting cost-based weights over a 3-year transition period beginning in FY 2007 and making interim changes to the DRG system for FY 2007 by creating 20 new CMS DRGs and modifying 32 other DRGs across 13 different clinical areas involving nearly 1.7 million cases. As described in more detail below, these refinements were intermediate steps towards comprehensive reform of both the relative weights and the DRG system as we undertook further study. For FY 2008, we adopted 745 new Medicare Severity DRGs (MS–DRGs) to replace the CMS DRGs. We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a full detailed discussion of how the MS–DRG system, based on severity levels of illness, was established (72 FR 47141).

Currently, cases are classified into MS–DRGs for payment under the IPPS based on the following information reported by the hospital: The principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay. (We refer readers to section II.G.11.c. of this proposed rule for a discussion of our efforts to increase our internal systems capacity to process diagnosis and procedures on hospital claims to 25 diagnosis codes and 25 procedure codes prior to the use of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10 PCS) for inpatient hospital procedure coding, effective October 1, 2013.) In a small number of MS–DRGs, classification is also based on the age, sex, and discharge status of the patient. The diagnosis and procedure information is reported by the hospital using codes from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) prior to October 1, 2013. We refer readers to section II.G.11.b. of this proposed rule for a reference to the replacement of ICD–9–CM, Volumes 1 and 2, including the Official ICD–9–CM Guidelines for Coding and Reporting, Volume 3, with the ICD–10–CM and ICD–10–PCS, including the Official ICD–10–CM and ICD–10–PCS Guidelines for Coding and Reporting, effective October 1, 2013 (FY 2014).

The process of developing the MS–DRGs was begun by dividing all possible principal diagnoses into mutually exclusive principal diagnosis areas, referred to as Major Diagnostic Categories (MDCs). The MDCs were formulated by physician panels to ensure that the DRGs would be clinically coherent. The diagnoses in each MDC correspond to a single organ system or etiology and, in general, are associated with a particular medical specialty. Thus, in order to maintain the requirement of clinical coherence, no final MS–DRG could contain patients in different MDCs. For example, MDC 6 is Diseases and Disorders of the Digestive System. This approach is used because clinical care is generally organized in accordance with the organ system affected. However, some MDCs are not constructed on this basis because they involve multiple organ systems (for example, MDC 22 (Burns)). For FY 2011, cases were assigned to one of 747 MS–DRGs in 25 MDCs. The table below lists the 25 MDCs.

[1] Medicare Payment Advisory Commission: *Report to the Congress, Physician-Owned Specialty Hospitals,* March 2005, page viii.

	Major Diagnostic Categories (MDCs)
1	Diseases and Disorders of the Nervous System
2	Diseases and Disorders of the Eye
3	Diseases and Disorders of the Ear, Nose, Mouth, and Throat
4	Diseases and Disorders of the Respiratory System
5	Diseases and Disorders of the Circulatory System
6	Diseases and Disorders of the Digestive System
7	Diseases and Disorders of the Hepatobiliary System and Pancreas
8	Diseases and Disorders of the Musculoskeletal System and Connective Tissue
9	Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast
10	Endocrine, Nutritional and Metabolic Diseases and Disorders
11	Diseases and Disorders of the Kidney and Urinary Tract
12	Diseases and Disorders of the Male Reproductive System
13	Diseases and Disorders of the Female Reproductive System
14	Pregnancy, Childbirth, and the Puerperium
15	Newborns and Other Neonates with Conditions Originating in the Perinatal Period
16	Diseases and Disorders of the Blood and Blood Forming Organs and Immunological Disorders
17	Myeloproliferative Diseases and Disorders and Poorly Differentiated Neoplasms
18	Infectious and Parasitic Diseases (Systemic or Unspecified Sites)
19	Mental Diseases and Disorders
20	Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders
21	Injuries, Poisonings, and Toxic Effects of Drugs
22	Burns
23	Factors Influencing Health Status and Other Contacts with Health Services
24	Multiple Significant Trauma
25	Human Immunodeficiency Virus Infections

In general, cases are assigned to an MDC based on the patient's principal diagnosis before assignment to an MS–DRG. However, under the most recent version of the Medicare GROUPER (Version 28.0), there are 13 MS–DRGs to which cases are directly assigned on the basis of ICD–9–CM procedure codes. These MS–DRGs are for heart transplant or implant of heart assist systems; liver and/or intestinal transplants; bone marrow transplants; lung transplants; simultaneous pancreas/kidney transplants; pancreas transplants; and tracheostomies. Cases are assigned to these MS–DRGs before they are classified to an MDC. The table below lists the 13 current pre-MDCs.

Pre-Major Diagnostic Categories (Pre-MDCs)	
MS-DRG 001	Heart Transplant or Implant of Heart Assist System with MCC
MS-DRG 002	Heart Transplant or Implant of Heart Assist System without MCC
MS-DRG 003	ECMO or Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except for Face, Mouth, and Neck Diagnosis with Major O.R.
MS-DRG 004	Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except for Face, Mouth, and Neck Diagnosis with Major O.R.
MS-DRG 005	Liver Transplant with MCC or Intestinal Transplant
MS-DRG 006	Liver Transplant without MCC
MS-DRG 007	Lung Transplant
MS-DRG 008	Simultaneous Pancreas/Kidney Transplant
MS-DRG 009	Bone Marrow Transplant
MS-DRG 010	Pancreas Transplant
MS-DRG 011	Tracheostomy for Face, Mouth, and Neck Diagnoses with MCC
MS-DRG 012	Tracheostomy for Face, Mouth, and Neck Diagnoses with CC
MS-DRG 013	Tracheostomy for Face, Mouth, and Neck Diagnoses without CC/MCC

Once the MDCs were defined, each MDC was evaluated to identify those additional patient characteristics that would have a consistent effect on hospital resource consumption. Because the presence of a surgical procedure that required the use of the operating room would have a significant effect on the type of hospital resources used by a patient, most MDCs were initially divided into surgical DRGs and medical DRGs. Surgical DRGs are based on a hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. Medical DRGs generally are differentiated on the basis of diagnosis and age (0 to 17 years of age or greater than 17 years of age). Some surgical and medical DRGs are further differentiated based on the presence or absence of a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

Generally, nonsurgical procedures and minor surgical procedures that are not usually performed in an operating room are not treated as O.R. procedures. However, there are a few non-O.R. procedures that do affect MS–DRG assignment for certain principal diagnoses. An example is extracorporeal shock wave lithotripsy for patients with a principal diagnosis of urinary stones. Lithotripsy procedures are not routinely performed in an operating room. Therefore, lithotripsy codes are not classified as O.R. procedures. However, our clinical advisors believe that patients with urinary stones who undergo extracorporeal shock wave lithotripsy should be considered similar to other patients who undergo O.R. procedures. Therefore, we treat this group of patients similar to patients undergoing O.R. procedures.

Once the medical and surgical classes for an MDC were formed, each diagnosis class was evaluated to determine if complications or comorbidities would consistently affect hospital resource consumption. Each diagnosis was categorized into one of three severity levels. These three levels include a major complication or comorbidity (MCC), a complication or comorbidity (CC), or a non-CC. Physician panels classified each diagnosis code based on a highly iterative process involving a combination of statistical results from test data as well as clinical judgment. As stated earlier, we refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a full detailed discussion of how the MS–DRG system was established based on severity levels of illness (72 FR 47141).

A patient's diagnosis, procedure, discharge status, and demographic information is entered into the Medicare claims processing systems and subjected to a series of automated screens called the Medicare Code Editor (MCE). The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

After patient information is screened through the MCE and further development of the claim is conducted, the cases are classified into the appropriate MS–DRG by the Medicare GROUPER software program. The GROUPER program was developed as a means of classifying each case into an MS–DRG on the basis of the diagnosis and procedure codes and, for a limited number of MS–DRGs, demographic information (that is, sex, age, and discharge status).

After cases are screened through the MCE and assigned to an MS–DRG by the GROUPER, the PRICER software calculates a base MS–DRG payment. The PRICER calculates the payment for each case covered by the IPPS based on the MS–DRG relative weight and additional factors associated with each hospital, such as IME and DSH payment adjustments. These additional factors increase the payment amount to hospitals above the base MS–DRG payment.

The records for all Medicare hospital inpatient discharges are maintained in the Medicare Provider Analysis and Review (MedPAR) file. The data in this file are used to evaluate possible MS–DRG classification changes and to recalibrate the MS–DRG weights. However, in the FY 2000 IPPS final rule (64 FR 41499 and 41500), we discussed a process for considering non-MedPAR data in the recalibration process. We stated that for use of non-MedPAR data

to be feasible for purposes of DRG recalibration and reclassification, the data must, among other things: (1) Be independently verified; (2) reflect a complete set of cases (or a representative sample of cases); and (3) enable us to calculate appropriate DRG relative weights and ensure that cases are classified to the "correct" DRG, and to one DRG only, in the recalibration process. Further, in order for us to consider using particular non-MedPAR data, we must have sufficient time to evaluate and test the data. The time necessary to do so depend upon the nature and quality of the non-MedPAR data submitted. Generally, however, a significant sample of the non-MedPAR data should be submitted by mid-October for consideration in conjunction with the next year's proposed rule. This date allows us time to test the data and make a preliminary assessment as to the feasibility of using the data. Subsequently, a complete non-MedPAR database should be submitted by early December for consideration in conjunction with the next year's proposed rule.

As we indicated above, for FY 2008, we made significant improvements in the DRG system to recognize severity of illness and resource usage by adopting MS–DRGs that were reflected in the FY 2008 GROUPER, Version 25.0, and were effective for discharges occurring on or after October 1, 2007. Our MS–DRG analysis for this FY 2012 proposed rule is based on data from the September 2010 update of the FY 2010 MedPAR file, which contained hospital bills received through September 30, 2010, for discharges occurring through September 30, 2010.

2. Yearly Review for Making MS–DRG Changes

Many of the changes to the MS–DRG classifications we make annually are the result of specific issues brought to our attention by interested parties. We encourage individuals with comments about MS–DRG classifications to submit these comments no later than early December of each year so they can be carefully considered for possible inclusion in the annual proposed rule and, if included, may be subjected to public review and comment. Therefore, similar to the timetable for interested parties to submit non-MedPAR data for consideration in the MS–DRG recalibration process, comments about MS–DRG classification issues should be submitted no later than early December in order to be considered and possibly included in the next annual proposed rule updating the IPPS.

The actual process of forming the MS–DRGs was, and will likely continue to be, highly iterative, involving a combination of statistical results from test data combined with clinical judgment. In the FY 2008 IPPS final rule (72 FR 47140 through 47189), we described in detail the process we used to develop the MS–DRGs that we adopted for FY 2008. In addition, in deciding whether to make further modification to the MS–DRGs for particular circumstances brought to our attention, we considered whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS–DRG. We evaluated patient care costs using average charges and lengths of stay as proxies for costs and relied on the judgment of our medical advisors to decide whether patients are clinically distinct or similar to other patients in the MS–DRG. In evaluating resource costs, we considered both the absolute and percentage differences in average charges between the cases we selected for review and the remainder of cases in the MS–DRG. We also considered variation in charges within these groups; that is, whether observed average differences were consistent across patients or attributable to cases that were extreme in terms of charges or length of stay, or both. Further, we considered the number of patients who will have a given set of characteristics and generally preferred not to create a new MS–DRG unless it would include a substantial number of cases.

C. Adoption of the MS–DRGs in FY 2008

In the FY 2006, FY 2007, and FY 2008 IPPS final rules, we discussed a number of recommendations made by MedPAC regarding revisions to the DRG system used under the IPPS (70 FR 47473 through 47482; 71 FR 47881 through 47939; and 72 FR 47140 through 47189). As we noted in the FY 2006 IPPS final rule, we had insufficient time to complete a thorough evaluation of these recommendations for full implementation in FY 2006. However, we did adopt severity-weighted cardiac DRGs in FY 2006 to address public comments on this issue and the specific concerns of MedPAC regarding cardiac surgery DRGs. We also indicated that we planned to further consider all of MedPAC's recommendations and thoroughly analyze options and their impacts on the various types of hospitals in the FY 2007 IPPS proposed rule.

For FY 2007, we began this process. In the FY 2007 IPPS proposed rule, we proposed to adopt Consolidated Severity DRGs (CS DRGs) for FY 2008 (if not earlier). Based on public comments received on the FY 2007 IPPS proposed rule, we decided not to adopt the CS DRGs. In the FY 2007 IPPS final rule (71 FR 47906 through 47912), we discussed several concerns raised by public commenters regarding the proposal to adopt CS DRGs. We acknowledged the many public comments suggesting the logic of Medicare's DRG system should continue to remain in the public domain as it has since the inception of the PPS. We also acknowledged concerns about the impact on hospitals and software vendors of moving to a proprietary system. Several commenters suggested that CMS refine the existing DRG classification system to preserve the many policy decisions that were made over the last 20 years and were already incorporated into the DRG system, such as complexity of services and new device technologies. Consistent with the concerns expressed in the public comments, this option had the advantage of using the existing DRGs as a starting point (which was already familiar to the public) and retained the benefit of many DRG decisions that were made in recent years. We stated our belief that the suggested approach of incorporating severity measures into the existing DRG system was a viable option that would be evaluated.

Therefore, we decided to make interim changes to the existing DRGs for FY 2007 by creating 20 new DRGs involving 13 different clinical areas that would significantly improve the CMS DRG system's recognition of severity of illness. We also modified 32 DRGs to better capture differences in severity. The new and revised DRGs were selected from 40 existing CMS DRGs that contained 1,666,476 cases and represented a number of body systems. In creating these 20 new DRGs, we deleted 8 existing DRGs and modified 32 existing DRGs. We indicated that these interim steps for FY 2007 were being taken as a prelude to more comprehensive changes to better account for severity in the DRG system by FY 2008.

In the FY 2007 IPPS final rule (71 FR 47898), we indicated our intent to pursue further DRG reform through two initiatives. First, we announced that we were in the process of engaging a contractor to assist us with evaluating alternative DRG systems that were raised as potential alternatives to the CMS DRGs in the public comments. Second, we indicated our intent to review over 13,000 ICD–9–CM diagnosis codes as part of making further refinements to the current CMS DRGs to better recognize severity of illness based

on the work that CMS (then HCFA) did in the mid-1990's in connection with adopting severity DRGs. We describe below the progress we have made on these two initiatives and our actions for FYs 2008, 2009, 2010, and 2011, and our proposed actions for FY 2012 based on our continued analysis of reform of the DRG system. We note that the adoption of the MS–DRGs to better recognize severity of illness has implications for the outlier threshold, the application of the postacute care transfer policy, the measurement of real case-mix versus apparent case-mix, and the IME and DSH payment adjustments. We discuss these implications for FY 2012 in other sections of this preamble and in the Addendum to this proposed rule.

In the FY 2007 IPPS proposed rule, we discussed MedPAC's recommendations to move to a cost-based HSRV weighting methodology using HSRVs beginning with the FY 2007 IPPS proposed rule for determining the DRG relative weights. Although we proposed to adopt the HSRV weighting methodology for FY 2007, we decided not to adopt the proposed methodology in the final rule after considering the public comments we received on the proposal. Instead, in the FY 2007 IPPS final rule, we adopted a cost-based weighting methodology without the HSRV portion of the proposed methodology. The cost-based weights were adopted over a 3-year transition period in ⅓ increments between FY 2007 and FY 2009. In addition, in the FY 2007 IPPS final rule, we indicated our intent to further study the HSRV-based methodology as well as other issues brought to our attention related to the cost-based weighting methodology adopted in the FY 2007 final rule. There was significant concern in the public comments that our cost-based weighting methodology does not adequately account for charge compression—the practice of applying a higher percentage charge markup over costs to lower cost items and services and a lower percentage charge markup over costs to higher cost items and services. Further, public commenters expressed concern about potential inconsistencies between how costs and charges are reported on the Medicare cost reports and charges on the Medicare claims. In the FY 2007 IPPS final rule, we used costs and charges from the cost reports to determine departmental level cost-to-charge ratios (CCRs) which we then applied to charges on the Medicare claims to determine the cost-based weights. The commenters were concerned about potential distortions to the cost-based weights that would result from inconsistent reporting between the cost reports and the Medicare claims. After publication of the FY 2007 IPPS final rule, we entered into a contract with RTI International (RTI) to study both charge compression and the extent, if any, to which our methodology for calculating DRG relative weights is affected by inconsistencies between how hospitals report costs and charges on the cost reports and how hospitals report charges on individual claims. Further, as part of its study of alternative DRG systems, the RAND Corporation analyzed the HSRV cost-weighting methodology. We refer readers to section II.E. of the preamble of this proposed rule for a discussion of the issue of charge compression and the cost-weighting methodology for FY 2012.

We believe that revisions to the DRG system to better recognize severity of illness and changes to the relative weights based on costs rather than charges are improving the accuracy of the payment rates in the IPPS. We agree with MedPAC that these refinements should be pursued. Although we continue to caution that any prospective payment system based on grouping cases will always present some opportunities for providers to specialize in cases they believe have higher margins, we believe that the changes we have adopted and the continuing reforms we are proposing to make in this proposed rule for FY 2012 will improve payment accuracy and reduce financial incentives to create specialty hospitals.

We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a full discussion of how the MS–DRG system was established based on severity levels of illness (72 FR 47141).

D. Proposed FY 2012 MS–DRG Documentation and Coding Adjustment, Including the Applicability to the Hospital-Specific Rates and the Puerto Rico-Specific Standardized Amount

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90

As we discussed earlier in this preamble, we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, there are 747 MS–DRGs, and we are proposing 4 additional MS–DRGs for FY 2012.) By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

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

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110–90. Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percent for FY 2008 and −0.9 percent for FY 2009. Section 7(a) of Public Law 110–90 did not adjust the FY 2010 −1.8 percent documentation and coding adjustment promulgated in the FY 2008 IPPS final rule with comment period. To comply with section 7(a) of Public Law 110–90, we promulgated a final rule on November 27, 2007 (72 FR 66886) that modified the IPPS documentation and coding adjustment for FY 2008 to −0.6 percent, and revised the FY 2008 payment rates, factors, and thresholds accordingly. These revisions were effective on October 1, 2007.

For FY 2009, section 7(a) of Pub. L. 110–90 required a documentation and coding adjustment of −0.9 percent instead of the −1.8 percent adjustment established in the FY 2008 IPPS final

rule with comment period. As discussed in the FY 2009 IPPS final rule (73 FR 48447) and required by statute, we applied a documentation and coding adjustment of −0.9 percent to the FY 2009 IPPS national standardized amount. The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, as amended by Public Law 110–90, are cumulative. As a result, the −0.9 percent documentation and coding adjustment for FY 2009 was in addition to the −0.6 percent adjustment for FY 2008, yielding a combined effect of −1.5 percent.

2. Prospective Adjustment to the Average Standardized Amounts Required by Section 7(b)(1)(A) of Public Law 110–90

Section 7(b)(1)(A) of Public Law 110–90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, the Secretary shall make an appropriate adjustment under section 1886(d)(3)(A)(vi) of the Act. Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 reflected the change that occurred in those years.

3. Recoupment or Repayment Adjustments in FYs 2010 Through 2012 Required by Public Law 110–90

If, based on a retroactive evaluation of claims data, the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different from the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an additional adjustment to the standardized amounts under section 1886(d) of the Act. This adjustment must offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Public Law 110–90. This adjustment is in addition to making an appropriate adjustment to the standardized amounts under section 1886(d)(3)(A)(vi) of the Act as required by section 7(b)(1)(A) of Public Law 110–90. That is, these adjustments are intended to recoup (or repay, in the case of underpayments) spending in excess of (or less than) spending that would have occurred had the prospective adjustments for changes in documentation and coding applied in FY 2008 and FY 2009 precisely matched the changes that occurred in those years. Public Law 110–90 requires that the Secretary make these recoupment or repayment adjustments for discharges occurring during FYs 2010, 2011, and 2012.

4. Retrospective Evaluation of FY 2008 and FY 2009 Claims Data

In order to implement the requirements of section 7 of Public Law 110–90, we indicated in the FY 2009 IPPS final rule (73 FR 48450) that we planned a thorough retrospective evaluation of our claims data. We stated that the results of this evaluation would be used by our actuaries to determine any necessary payment adjustments to the standardized amounts under section 1886(d) of the Act to ensure the budget neutrality of the MS–DRGs implementation for FY 2008 and FY 2009, as required by law. In the FY 2009 IPPS proposed rule (73 FR 23541 through 23542), we described our preliminary plan for a retrospective analysis of inpatient hospital claims data and invited public input on our proposed methodology.

In that proposed rule, we indicated that we intended to measure and corroborate the extent of the overall national average changes in case-mix for FY 2008 and FY 2009. We expected that the two largest parts of this overall national average change would be attributable to underlying changes in actual patient severity of illness and to documentation and coding improvements under the MS–DRG system. In order to separate the two effects, we planned to isolate the effect of shifts in cases among base DRGs from the effect of shifts in the types of cases within base DRGs.

The MS–DRGs divide the base DRGs into three severity levels (with MCC, with CC, and without CC); the previously used CMS DRGs had only two severity levels (with CC and without CC). Under the CMS DRG system, the majority of hospital discharges had a secondary diagnosis which was on the CC list, which led to the higher severity level. The MS–DRGs significantly changed the code lists of what was classified as an MCC or a CC. Many codes that were previously classified as a CC are no longer included on the MS–DRG CC list because the data and clinical review showed these conditions did not lead to a significant increase in resource use. The addition of a new level of high severity conditions, the MCC list, also provided a new incentive to code more precisely in order to increase the severity level. We anticipated that hospitals would examine the MS–DRG MCC and CC code lists and then work with physicians and coders on documentation and coding practices so that coders could appropriately assign codes from the highest possible severity level. We note that there have been numerous seminars and training sessions on this particular coding issue. The topic of improving documentation practices in order to code conditions on the MCC list was also discussed extensively by participants at the March 11–12, 2009 ICD–9–CM Coordination and Maintenance Committee meeting. Participants discussed their hospitals' efforts to encourage physicians to provide more precise documentation so that coders could appropriately assign codes that would lead to a higher severity level. Because we expected most of the documentation and coding changes under the MS–DRG system would occur in the secondary diagnoses, we believed that the shifts among base DRGs were less likely to be the result of the MS–DRG system and the shifts within base DRGs were more likely to be the result of the MS–DRG system. We also anticipated evaluating data to identify the specific MS–DRGs and diagnoses that contributed significantly to the documentation and coding payment effect and to quantify their impact. This step entailed analysis of the secondary diagnoses driving the shifts in severity within specific base DRGs.

In the FY 2009 IPPS proposed rule, we solicited public comments on the analysis plans described above, as well as suggestions on other possible approaches for performing a retrospective analysis to identify the amount of case-mix changes that occurred in FY 2008 and FY 2009 that did not reflect real increases in patient severity of illness.

A few commenters, including MedPAC, expressed support for the analytic approach described in the FY

2009 IPPS proposed rule. A number of other commenters expressed concerns about certain aspects of the approach and/or suggested alternate analyses or study designs. In addition, one commenter recommended that any determination or retrospective evaluation by the actuaries of the impact of the MS–DRGs on case-mix be open to public scrutiny prior to the implementation of the payment adjustments beginning in FY 2010.

We took these comments into consideration as we developed our proposed analysis plan, and in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24092 through 24101), we solicited public comment on our methodology and analysis. For the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, we performed a retrospective evaluation of the FY 2008 data for claims paid through December 2008. Based on this evaluation, our actuaries determined that implementation of the MS–DRG system resulted in a 2.5 percent change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43768 through 43772), we responded to comments on our methodology for the retrospective evaluation of FY 2008 claims data. We refer readers to that final rule for a detailed description of our analysis and prior responses to comments.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50068), we performed the same analysis for FY 2009 claims data using the same methodology as we did for FY 2008 claims. We note that, in the FY 2011 IPPS/LTCH PPS proposed rule, we performed this analysis using FY 2009 claims paid through December 2009. In the FY 2011 IPPS/LTCH PPS final rule, we updated the analysis with FY 2009 claims paid through March 2010, as we discussed in the proposed rule. We note that, for all IPPS hospitals, other than those in Puerto Rico, the estimates were unchanged from those in the proposed rule. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50068) for a detailed description of our analysis and prior responses to comments. The results of the analysis for the FY 2011 proposed and final rules provided additional support for our conclusion that the proposed 5.4 percent estimate accurately reflected the FY 2009 increases in documentation and coding under the MS–DRG system.

As in prior years, the FY 2008 and FY 2009 MedPAR files are available to the public to allow independent analysis of the FY 2008 and FY 2009 documentation and coding effect. Interested individuals may still order these files through the Web site at: *http://www.cms.hhs.gov/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the file and provides directions and further detailed instructions for how to order.

Persons placing an order must send the following: A Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check for $3,655 to:

Mailing address if using the U.S. Postal Service: Centers for Medicare & Medicaid Services, RDDC Account, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520.

Mailing address if using express mail: Centers for Medicare & Medicaid Services, OFM/Division of Accounting—RDDC, 7500 Security Boulevard, C3–07–11, Baltimore, MD 21244–1850.

5. Prospective Adjustment for FY 2010 and Subsequent Years Authorized by Section 7(b)(1)(A) of Public Law 110–90 and Section 1886(d)(3)(vi) of the Act

Based on our evaluation of FY 2008 Medicare claims data that were most current at the time of the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, the estimated 2.5 percent change in FY 2008 case-mix due to changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 exceeded the −0.6 percent prospective documentation and coding adjustment applied under section 7(a) of Public Law 110–90 by 1.9 percentage points. In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24096), we solicited public comment on our proposal to make a −1.9 percent prospective adjustment to the standardized amounts under section 1886(d) of the Act to address the effects of documentation and coding changes unrelated to changes in real case-mix in FY 2008. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, in response to public comments, we indicated that we fully understood that our proposed adjustment of −1.9 percent would reduce the increase in payments that affected hospitals would have received in FY 2009 in the absence of the adjustment, and we determined that it would be appropriate to postpone adopting documentation and coding adjustments as authorized under section 7(a) of Public Law 110–90 and section 1886(d)(3)(A)(vi) of the Act until a full analysis of case-mix changes could be completed. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43767 through 43777) for a detailed description of our proposal, responses to comments, and finalized policy.

After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 1.054. After accounting for the −0.6 percent and the −0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of −3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Public Law 110–90 to make an adjustment to the average standardized amounts in order to eliminate the full effect of the documentation and coding changes on future payments. Unlike section 7(b)(1)(B) of Public Law 110–90, section 7(b)(1)(A) does not specify when we must apply the prospective adjustment, but merely requires us to make an "appropriate" adjustment. Therefore, as we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50061), we believe we have some discretion as to the manner in which we apply the prospective adjustment of −3.9 percent. We indicated that applying the full prospective adjustment of −3.9 percent for FY 2011, in combination with the proposed recoupment adjustment of −2.9 percent in FY 2011 (discussed below) would require an aggregate adjustment of −6.8 percent. As we discuss elsewhere in this section II.D., and more extensively in the FY 2011 IPPS/LTCH PPS final rule, it has been our practice to moderate payment adjustments when necessary to mitigate the effects of significant downward adjustments on hospitals, to avoid what could be widespread, disruptive effects of such adjustments on hospitals. As we also discuss below in this section II.D., we are required to implement the remaining adjustment in section 7(b)(1)(B) of Public Law 110–90 no later than the FY 2012 rulemaking period, and accordingly, in the FY 2011 IPPS/LTCH PPS proposed rule, we proposed a recoupment adjustment under section 7(b)(1)(B) of −2.9 percent for FY 2011 (75 FR 23870 and 23871). Therefore, we stated that we believed it was appropriate to not implement any or all of the −3.9 percent prospective adjustment in FY 2011. Accordingly, we did not propose a prospective

adjustment under section 7(b)(1)(A) of Public Law 110–90 for FY 2011 (75 FR 23868 through 23870) for FY 2011. We note that, as a result, payments in FY 2011 (and in each future year until we implement the requisite adjustment) would be 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90. Our actuaries estimate that this 3.9 percentage point increase will result in an aggregate payment of approximately $4 billion. We also noted that payments in FY 2010 were also expected to be 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90, which our actuaries estimated increased aggregate payments by approximately $4 billion in FY 2010.

Because further delay of this prospective adjustment will result in a continued accrual of unrecoverable overpayments, it is imperative that we propose a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we are proposing a −3.15 percent prospective adjustment to the standardized amount to partially eliminate the full effect of the documentation and coding changes on future payments. Due to the offsetting nature of the remaining recoupment adjustment under section 7(b)(1)(B) of Public Law 110–90 (described below in section II.D.6. of this preamble), and after considering other payment adjustments to FY 2012 rates proposed elsewhere within this proposed rule, we believe that the proposed −3.15 percent adjustment will allow for a significant reduction in potential unrecoverable overpayments, yet will maintain a comparable adjustment level between FY 2011 and FY 2012, reflecting the applicable percentage increase with a documentation and coding adjustment. We recognize that an additional adjustment of −0.75 (3.9 minus 3.15) percent will be required in future rule making to complete the necessary −3.9 adjustment to meet CMS' statutory requirement under section 7(b)(1)(A) of Public Law 110–90. We are not at this time proposing a timeline to implement the remainder of this prospective adjustment.

6. Recoupment or Repayment Adjustment for FY 2010 Authorized by Section 7(b)(1)(B) of Public Law 110–90

As discussed in section II.D.1. of this preamble, section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an adjustment to the standardized amounts under section 1886(d) of the Act to offset the estimated increase or decrease in aggregate payments for FY 2008 and FY 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustments applied under section 7(a) of Public Law 110–90. This determination must be based on a retrospective evaluation of claims data.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43773), we estimated a 2.5 percent change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008, exceeding the −0.6 percent prospective documentation and coding adjustment applied under section 7(a) of Public Law 110–90 by 1.9 percentage points. We stated that our actuaries had estimated that this 1.9 percentage point increase resulted in an increase in aggregate payments of approximately $2.2 billion in FY 2008. We did not propose to make an adjustment to the FY 2010 average standardized amounts to offset, in whole or in part, the estimated increase in aggregate payments for discharges occurring in FY 2008, but stated in the proposed rule that we intended to address this issue in future rulemaking. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43774), we stated that because we would not receive all FY 2009 claims data prior to publication of the final rule, we would address any increase or decrease in FY 2009 payments in future rulemaking for FY 2011 and 2012 after we performed a retrospective evaluation of the FY 2009 claims data. In response to public comments in FY 2010, we indicated that we recognized that any adjustment to account for the documentation and coding effect observed in the FY 2008 and FY 2009 claims data may result in significant future payment reductions for providers. However, we indicated that we are required under section 7(b)(1)(B) of Pub. L. 110–90 to recover the difference of actual documentation and coding effect in FY 2008 and FY 2009 that is greater than the prior adjustments. We agreed with the commenters who requested that CMS delay any adjustment and, for the reasons stated above, indicated that we expected to address this issue in the FY 2011 rulemaking. We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43767 through 43777) for a detailed description of our proposal, responses to comments, and finalized policy.

As we indicated in the FY 2011 IPPS/LTCH PPS final rule, the change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 and FY 2009 exceeded the −0.6 and −0.9 percent prospective documentation and coding adjustments applied under section 7(a) of Pub. L. 110–90 for those 2 years, respectively, by 1.9 percentage points in FY 2008 and 3.9 percentage points in FY 2009. In total, this change exceeded the cumulative prospective adjustments by 5.8 (1.9 plus 3.9) percentage points. Our actuaries estimated that this 5.8 percentage point increase resulted in an increase in aggregate payments of approximately $6.9 billion. In the FY 2011 IPPS/LTCH PPS final rule, we noted that there may be a need to actuarially adjust the recoupment adjustment to accurately reflect accumulated interest. Therefore, we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012, subject to actuarial adjustment to reflect accumulated interest, would be necessary in order to meet the requirements of section 7(b)(1)(B) of Public Law 110–90 to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009. In the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23871), we stated that we intended to take into account the need to reflect accumulated interest in proposing a recoupment adjustment under section 7(b)(1)(B) of Public Law 110–90 for FY 2012.

It is often our practice to phase in rate adjustments over more than one year in order to moderate the effect on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, in the FY 2011 IPPS/LTCH PPS proposed rule, we proposed to make an adjustment to the standardized amount of −2.9 percent, representing approximately half of the aggregate adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. An adjustment of this magnitude would allow us to moderate the effects on hospitals in one year while simultaneously making it possible to implement the entire adjustment within the timeframe required under section 7(b)(1)(B) of Public Law 110–90 (that is, no later than FY 2012).

Unlike the permanent prospective adjustment to the standardized amounts under section 7(b)(1)(A) of Public Law 110–90 described earlier, the recoupment adjustment to the standardized amounts under section 7(b)(1)(B) of Public Law 110–90 is not cumulative, and, therefore, would be removed for subsequent fiscal years

once we have completely offset the increase in aggregate payments for discharges for FY 2008 and FY 2009 expenditures. In keeping with our practice of moderating payment adjustments when necessary, we stated that we anticipated that the proposal of phasing in the recoupment adjustment will have an additional, and significant, moderating effect on implementing the requirements of section 7(b)(1)(B) of Public Law 110–90 for FY 2012.

In the FY 2011 IPPS/LTCH PPS proposed rule, we sought public comment on our proposal to offset part of the total 5.8 percent increase in aggregate payments (including interest) for discharges occurring in FY 2008 and FY 2009 resulting from the adoption of the MS–DRGs in FY 2011, noting that this proposal would result in a −2.9 percent adjustment to the standardized amount. We received numerous comments on our proposal, especially from national and regional hospital associations, hospital systems, and individual hospitals. MedPAC also commented on our proposal. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50055 through 50073) for a detailed description of our analysis and prior responses to comments, and finalized policy.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50068), we finalized the proposed adjustment to the standardized amount of −2.9 percent, which represented approximately half of the aggregate recoupment adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. We were persuaded by both MedPAC's analysis, and our own review of the methodologies recommended by various commenters, that the methodology we employed to determine the required recoupment adjustment was sound. Since the statute required that we implement the entire recoupment adjustment no later than FY 2012, we have sought, as we commonly do, to moderate the potential impact on hospitals by phasing in the required adjustment over more than one year. As we stated in prior rulemaking, a major advantage of making the −2.9 percent adjustment to the standardized amount in FY 2011 was that, because the required recoupment adjustment is not cumulative, we anticipated removing the FY 2011 −2.9 percent adjustment from the rates (in other words, making a positive 2.9 percent adjustment to the rates) in FY 2012, at the same time that the law required us to apply the remaining approximately −2.9 percent adjustment required by section 7(b)(1)(B) of Public Law 110–90. These two steps in FY 2012, restoring the FY 2011 −2.9 percent adjustment and then applying the remaining adjustment of approximately −2.9 percent, would effectively cancel each other out. The result of these two steps would be an aggregate adjustment of approximately 0.0 percent. While we stated in the FY 2011 IPPS/LTCH PPS final rule the need to potentially adjust the remaining −2.9 percent estimate to account for accumulated interest, our actuaries have determined that there has been no significant interest accumulation and that no additional adjustment will be required. Therefore, for FY 2012, pursuant to the timeframes set forth by section 7(b)(1)(B) of Public Law 110–90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we are proposing to complete the recoupment adjustment by implementing the remaining −2.9 percent adjustment, in addition to removing the effect of the −2.9 percent adjustment to the standardized amount finalized for FY 2011. Because these adjustments will, in effect, balance out, there will be no year-to-year change in the standardized amount due to this recoupment adjustment. As this adjustment will complete the required recoupment for overpayments due to documentation and coding effects on discharges occurring in FYs 2008 and 2009, we anticipate removing the effect of this adjustment by adding 2.9 percent to the standardized amount in FY 2013. We continue to believe that this is a reasonable and fair approach that satisfies the requirements of the statute while substantially moderating the financial impact on hospitals.

FY 2012 MS-DRG Documentation and Coding Adjustment

	Required Prospective Adjustment for FYs 2008-2009	Remaining Required Recoupment Adjustment for FYs 2008-2009	Total Remaining Adjustment	Proposed Prospective Adjustment for FY 2012	Proposed Recoupment Adjustment to FY 2012 Payments	Remaining Prospective Adjustment If proposals are Finalized
Level of Adjustments	-3.9%	-2.9%	-6.8%	-3.15%	-2.9%	-0.75%

The table above summarizes the proposed adjustments for FY 2012 for documentation and coding for IPPS hospitals.

7. Background on the Application of the Documentation and Coding Adjustment to the Hospital-Specific Rates

Under section 1886(d)(5)(D)(i) of the Act, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge. Under section 1886(d)(5)(G) of the Act, MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate based on the greatest of the FY 1982, FY 1987, or FY 2002 costs per discharge. In the FY 2008 IPPS final rule with comment period (72 FR 47152 through 47188), we established a policy of applying the documentation and coding adjustment to the hospital-specific rates. In that final rule with comment period, we indicated that because SCHs and MDHs use the same DRG system as all other hospitals, we believe they should be equally subject to the budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. In establishing this policy, we relied on section 1886(d)(3)(A)(vi) of the Act, which provides us with the authority to adjust "the standardized amount" to eliminate the effect of changes in coding or classification that do not reflect real change in case-mix.

However, in the final rule that appeared in the **Federal Register** on November 27, 2007 (72 FR 66886), we rescinded the application of the

documentation and coding adjustment to the hospital-specific rates retroactive to October 1, 2007. In that final rule, we indicated that, while we still believe it would be appropriate to apply the documentation and coding adjustment to the hospital-specific rates, upon further review, we decided that the application of the documentation and coding adjustment to the hospital-specific rates is not consistent with the plain meaning of section 1886(d)(3)(A)(vi) of the Act, which only mentions adjusting "the standardized amount" under section 1886(d) of the Act and does not mention adjusting the hospital-specific rates.

In the FY 2009 IPPS proposed rule (73 FR 23540), we indicated that we continued to have concerns about this issue. Because hospitals paid based on the hospital-specific rate use the same MS–DRG system as other hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. In section 1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid based on the standardized amount should not receive additional payments based on the effect of documentation and coding changes that do not reflect real changes in case-mix. Similarly, we believe that hospitals paid based on the hospital-specific rates should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patient severity of illness. While we continue to believe that section 1886(d)(3)(A)(vi) of the Act does not provide explicit authority for application of the documentation and coding adjustment to the hospital-specific rates, we believe that we have the authority to apply the documentation and coding adjustment to the hospital-specific rates using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. The special exceptions and adjustment provision authorizes us to provide "for such other exceptions and adjustments to [IPPS] payment amounts * * * as the Secretary deems appropriate." In the FY 2009 IPPS final rule (73 FR 48448 through 48449), we indicated that, for the FY 2010 rulemaking, we planned to examine our FY 2008 claims data for hospitals paid based on the hospital-specific rate. We further indicated that if we found evidence of significant increases in case-mix for patients treated in these hospitals that do not reflect real changes in case-mix, we would consider proposing application of the documentation and coding adjustments to the FY 2010 hospital-specific rates under our authority in section 1886(d)(5)(I)(i) of the Act.

In response to public comments received on the FY 2009 IPPS proposed rule, we stated in the FY 2009 IPPS final rule that we would consider whether such a proposal was warranted for FY 2010. To gather information to evaluate these considerations, we indicated that we planned to perform analyses on FY 2008 claims data to examine whether there has been a significant increase in case-mix for hospitals paid based on the hospital-specific rate. If we found that application of the documentation and coding adjustment to the hospital-specific rates for FY 2010 was warranted, we indicated that we would propose to make such an adjustment in the FY 2010 IPPS proposed rule.

8. Documentation and Coding Adjustment to the Hospital-Specific Rates for FY 2011 and Subsequent Fiscal Years

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule and final rule (74 FR 24098 through 24100 and 74 FR 43775 through 43776, respectively), we discussed our retrospective evaluation of the FY 2008 claims data for SCHs and MDHs using the same methodology described earlier for other IPPS hospitals. We found that, independently for both SCHs and MDHs, the change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 slightly exceeded the proposed 2.5 percent result discussed earlier for other IPPS hospitals, but did not significantly differ from that result. We refer readers to those rules for a more complete discussion.

Therefore, consistent with our statements in prior IPPS rules, we proposed to use our authority under section 1886(d)(5)(I)(i) of the Act to prospectively adjust the hospital-specific rates by the proposed −2.5 percent in FY 2010 to account for our estimated documentation and coding effect in FY 2008 that does not reflect real changes in case-mix. We proposed to leave this adjustment in place for subsequent fiscal years in order to ensure that changes in documentation and coding resulting from the adoption of the MS–DRGs do not lead to an increase in aggregate payments for SCHs and MDHs not reflective of an increase in real case-mix. The proposed −2.5 percent adjustment to the hospital-specific rates exceeded the −1.9 percent adjustment to the national standardized amount under section 7(b)(1)(A) of Public Law 110–90 because, unlike the national standardized rates, the FY 2008 hospital-specific rates were not previously reduced in order to account for anticipated changes in documentation and coding that do not reflect real changes in case-mix resulting from the adoption of the MS–DRGs.

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24100), we solicited public comment on this proposal. Consistent with our approach for IPPS hospitals discussed earlier, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we also delayed adoption of a documentation and coding adjustment to the hospital-specific rate until FY 2011. We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule for a more detailed discussion of our proposal, responses to comments, and finalized policy.

As we have noted previously, because SCHs and MDHs use the same MS–DRG system as all other IPPS hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. Therefore, we believe they should be equally subject to a prospective budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. We believe the documentation and coding estimates for all subsection (d) hospitals should be the same. While the findings for the documentation and coding effect for all IPPS hospitals are similar to the effect for SCHs and slightly different to the effect for MDHs, we continue to believe that this is the appropriate policy so as to neither advantage or disadvantage different types of providers. As we discuss in section II.D.4. of this preamble, our best estimate, based on the most recently available data, is that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of the documentation and coding changes on future payments to SCHs and MDHs. Unlike the case of standardized amounts paid to IPPS hospitals, prior to FY 2011, we had not made any previous adjustments to the hospital-specific rates paid to SCHs and MDHs to account for documentation and coding changes. Therefore, the entire −5.4 percent recoupment adjustment needed to be made, as opposed to a −3.9 percent remaining adjustment for IPPS hospitals.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50068 through 50071), we made an adjustment to the standardized amount for IPPS hospitals of −2.9 percent under section 7(b)(1)(B) of

Public Law 110–90, for FY 2011. As we noted in the FY 2011 IPPS/LTCH PPS final rule, in determining the level and pace of adjustments to account for such documentation and coding changes, we believe that it is important to maintain, as much as possible, both consistency and equity among these classes of hospitals. Therefore, we finalized a prospective adjustment of −2.9 percent to the hospital-specific rates paid to SCHs and MDHs. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a more detailed discussion of our proposal, responses to comments, and finalized policy.

As discussed earlier in this section II.D., we are proposing a net −3.15 percent documentation and coding adjustment for IPPS hospitals in FY 2012 (−3.15 percent prospective adjustment plus a −2.9 percent recoupment adjustment in FY 2012, offset by the removal of the −2.9 percent recoupment adjustment for FY 2010). The proposed IPPS adjustment exceeds the remaining −2.5 percent documentation and coding adjustment for hospitals receiving a hospital-specific rate (that is, the entire −5.4 percent adjustment, minus the −2.9 percent adjustment finalized for FY 2011). As we indicated in the FY 2011 IPPS/LTCH PPS proposed rule and final rule, we are continuing, as much as possible, consistent with section 7(b)(1) of Public Law 110–90 and section 1886(d)(5)(I)(i) of the Act, to take such consistency and equity into account in developing future proposals for implementing documentation and coding adjustments. We believe that any adjustment to the hospital-specific rate due to documentation and coding effect should be as similar as possible to adjustments to the IPPS rate. Accordingly, we are proposing a −2.5 percent payment adjustment to the hospital-specific rate. We believe that proposing the entire remaining prospective adjustment of −2.5 percent allows CMS to maintain, to the extent possible, similarity and consistency in payment rates for different IPPS hospitals paid using the MS–DRG. As discussed below, we took a similar approach in finalizing an adjustment to the Puerto-Rico specific rate in FY 2011.

9. Application of the Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

a. Background

Puerto Rico hospitals are paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As noted previously, the documentation and coding adjustment we adopted in the FY 2008 IPPS final rule with comment period relied upon our authority under section 1886(d)(3)(A)(vi) of the Act, which provides the Secretary the authority to adjust "the standardized amounts computed under this paragraph" to eliminate the effect of changes in coding or classification that do not reflect real changes in case-mix. Section 1886(d)(3)(A)(vi) of the Act applies to the national standardized amounts computed under section 1886(d)(3) of the Act, but does not apply to the Puerto Rico-specific standardized amount computed under section 1886(d)(9)(C) of the Act. In calculating the FY 2008 payment rates, we made an inadvertent error and applied the FY 2008 –0.6 percent documentation and coding adjustment to the Puerto Rico-specific standardized amount, relying on our authority under section 1886(d)(3)(A)(vi) of the Act. However, section 1886(d)(3)(A)(vi) of the Act authorizes application of a documentation and coding adjustment to the national standardized amount and does not apply to the Puerto Rico specific standardized amount. In the FY 2009 IPPS final rule (73 FR 48449), we corrected this inadvertent error by removing the –0.6 percent documentation and coding adjustment from the FY 2008 Puerto Rico-specific rates (that is, we made a positive 0.6 percent adjustment, increasing the Puerto Rico-specific rates).

While section 1886(d)(3)(A)(vi) of the Act is not applicable to the Puerto Rico-specific standardized amount, we believe that we have the authority to apply the documentation and coding adjustment to the Puerto Rico-specific standardized amount using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. Similar to SCHs and MDHs that are paid based on the hospital-specific rate, we believe that Puerto Rico hospitals that are paid based on the Puerto Rico-specific standardized amount should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patient severity of illness. Consistent with the approach described for SCHs and MDHs, in the FY 2009 IPPS final rule (73 FR 48449), we indicated that we planned to examine our FY 2008 claims data for hospitals in Puerto Rico. We indicated in the FY 2009 IPPS proposed rule (73 FR 23541) that if we found evidence of significant increases in case-mix for patients treated in these hospitals, we would consider proposing to apply documentation and coding adjustments to the FY 2010 Puerto Rico-specific standardized amount under our authority in section 1886(d)(5)(I)(i) of the Act.

b. Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

For the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, we performed a retrospective evaluation of the FY 2008 claims data for Puerto Rico hospitals using the same methodology described earlier for IPPS hospitals paid under the national standardized amounts under section 1886(d) of the Act. We found that, for Puerto Rico hospitals, the increase in payments for discharges occurring during FY 2008 due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 was approximately 1.1 percent. However, as we note earlier for IPPS hospitals and hospitals receiving hospital-specific rates, if the estimated documentation and coding effect determined based on a full analysis of FY 2009 claims data was more or less than our then current estimates, it would change, possibly lessen, the anticipated cumulative adjustments that we had estimated we would have to make for the FY 2008 and FY 2009 combined adjustment. Therefore, we believed that it would be more prudent to delay implementation of the documentation and coding adjustment to allow for a more complete analysis of FY 2009 claims data for Puerto Rico hospitals.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43777), we indicated that, given these documentation and coding increases, consistent with our statements in prior IPPS rules, we would use our authority under section 1886(d)(5)(I)(i) of the Act to adjust the Puerto Rico-specific rate and solicited public comment on the proposed −1.1 percent prospective adjustment. However, in parallel to our decision to postpone adjustments to the Federal standardized amount, we also indicated that we were adopting a similar policy for the Puerto Rico-specific rate for FY 2010 and would consider the phase-in of this adjustment over an appropriate time period through future rulemaking. We noted that, as with the hospital-specific rates, the Puerto Rico-specific standardized amount had not previously been adjusted based on estimated changes in documentation and coding associated with the adoption of the MS–DRGs.

Consistent with our approach for IPPS hospitals for FY 2010, we indicated that

we would address in the FY 2011 rulemaking cycle any change in FY 2009 case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009.

As we have noted above, similar to SCHs and MDHs, hospitals in Puerto Rico use the same MS–DRG system as all other hospitals and we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. Therefore, we believe they should be equally subject to the prospective budget neutrality adjustment that we intend to apply to prospective payment rates for IPPS hospitals, including SCHs and MDHs, in order to eliminate the full effect of the documentation and coding changes associated with implementation of the MS–DRG system.

As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), using the same methodology we applied to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals, our best estimate, based on the then most recently available data (FY 2009 claims paid through March 2010), was that, for documentation and coding that occurred over FY 2008 and FY 2009, a cumulative adjustment of −2.6 percent was required to eliminate the full effect of the documentation and coding changes on future payments from the Puerto Rico-specific rate. As we stated above, we believe it important to maintain both consistency and equity among all hospitals paid on the basis of the same MS–DRG system. At the same time, however, we recognize that the estimated cumulative impact on aggregate payment rates resulting from implementation of the MS–DRG system was smaller for Puerto Rico hospitals as compared to IPPS hospitals and SCHs and MDHs. Therefore, in the FY 2011 IPPS LTCH PPS proposed rule (75 FR 23876), we proposed an adjustment to eliminate the full effect of the documentation and coding changes on the portion of future payments to Puerto Rico hospitals based on the Puerto Rico-specific rate. We stated that we believed that a full prospective adjustment was the most appropriate means to take into full account the effect of documentation and coding changes on payments, while maintaining equity as much as possible between hospitals paid on the basis of different prospective rates. We noted that our updated data analysis in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50072 through 50073) final rule showed that this adjustment would be −2.6 percent. The previous estimate in the proposed rule was a −2.4 percent adjustment.

One reason we proposed the full prospective adjustment for the Puerto Rico-specific rate in FY 2011 was to maintain equity as much as possible in the documentation and coding adjustments applied to various hospital rates in FY 2011. Because our proposal was to make an adjustment that represents the full adjustment that is warranted for the Puerto Rico-specific rate, we indicated that we did not anticipate proposing any additional adjustments to the this rate for documentation and coding effects.

Therefore, because the Puerto Rico-specific rate received a full prospective adjustment of −2.6 percent in FY 2011, we are proposing no further adjustment in this proposed rule for FY 2012.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

In the FY 2009 IPPS final rule (73 FR 48450), we continued to implement significant revisions to Medicare's inpatient hospital rates by completing our 3-year transition from charge-based relative weights to cost-based relative weights. Beginning in FY 2007, we implemented relative weights based on cost report data instead of based on charge information. We had initially proposed to develop cost-based relative weights using the hospital-specific relative value cost center (HSRVcc) methodology as recommended by MedPAC. However, after considering concerns expressed in the public comments we received on the proposal, we modified MedPAC's methodology to exclude the hospital-specific relative weight feature. Instead, we developed national CCRs based on distinct hospital departments and engaged a contractor to evaluate the HSRVcc methodology for future consideration. To mitigate payment instability due to the adoption of cost-based relative weights, we decided to transition cost-based weights over 3 years by blending them with charge-based weights beginning in FY 2007. (We refer readers to the FY 2007 IPPS final rule for details on the HSRVcc methodology and the 3-year transition blend from charge-based relative weights to cost-based relative weights (71 FR 47882 through 47898).)

In FY 2008, we adopted severity-based MS–DRGs, which increased the number of DRGs from 538 to 745. Many commenters raised concerns as to how the transition from charge-based weights to cost-based weights would continue with the introduction of new MS–DRGs. We decided to implement a 2-year transition for the MS–DRGs to coincide with the remainder of the transition to cost-based relative weights. In FY 2008, 50 percent of the relative weight for each DRG was based on the CMS DRG relative weight and 50 percent was based on the MS–DRG relative weight.

In FY 2009, the third and final year of the transition from charge-based weights to cost-based weights, we calculated the MS–DRG relative weights based on 100 percent of hospital costs. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a more detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS–DRGs.

2. Summary of the RTI Study of Charge Compression and CCR Refinement

As we transitioned to cost-based relative weights, some public commenters raised concerns about potential bias in the weights due to "charge compression," which is the practice of applying a higher percentage charge markup over costs to lower cost items and services, and a lower percentage charge markup over costs to higher cost items and services. As a result, the cost-based weights would undervalue high-cost items and overvalue low-cost items if a single CCR is applied to items of widely varying costs in the same cost center. To address this concern, in August 2006, we awarded a contract to RTI to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the CCRs across services within cost centers. RTI issued an interim draft report in January 2007 with its findings on charge compression (which was posted on the CMS Web site at: *http://www.cms.hhs.gov/reports/downloads/Dalton.pdf*). In that report, RTI found that a number of factors contribute to charge compression and affect the accuracy of the relative weights. RTI's findings demonstrated that charge compression exists in several CCRs, most notably in the Medical Supplies and Equipment CCR.

In its interim draft report, RTI offered a number of recommendations to mitigate the effects of charge compression, including estimating regression-based CCRs to disaggregate the Medical Supplies Charged to Patients, Drugs Charged to Patients, and Radiology cost centers, and adding new cost centers to the Medicare cost report, such as adding a "Devices, Implants and Prosthetics" line under "Medical

Supplies Charged to Patients" and a "CT Scanning and MRI" subscripted line under "Radiology-Diagnostics". Despite receiving public comments in support of the regression-based CCRs as a means to immediately resolve the problem of charge compression, particularly within the Medical Supplies and Equipment CCR, we did not adopt RTI's recommendation to create additional regression-based CCRs. (For more details on RTI's findings and recommendations, we refer readers to the FY 2009 IPPS final rule (73 FR 48452).) RTI subsequently expanded its analysis of charge compression beyond inpatient services to include a reassessment of the regression-based CCR models using both outpatient and inpatient charge data. This interim report was made available in April 2008 during the public comment period on the FY 2009 IPPS proposed rule and 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_200804.pdf* . The IPPS-specific chapters, which were separately displayed in the April 2008 interim report, as well as the more recent OPPS chapters, were included in the July 3, 2008 RTI final report entitled, "Refining Cost-to-Charge Ratios for Calculating APC [Ambulatory Payment Classification] and DRG Relative Payment Weights," that became available at the time of the development of the FY 2009 IPPS final rule. 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.*

RTI's final report found that, under the IPPS and the OPPS, accounting improvements to the cost reporting data reduce some of the sources of aggregation bias without having to use regression-based adjustments. In general, with respect to the regression-based adjustments, RTI confirmed the findings of its March 2007 report that regression models are a valid approach for diagnosing potential aggregation bias within selected services for the IPPS and found that regression models are equally valid for setting payments under the OPPS.

RTI also noted that cost-based weights are only one component of a final prospective payment rate. There are other rate adjustments (wage index, IME, and DSH) to payments derived from the revised cost-based weights, and the cumulative effect of these components may not improve the ability of final payment to reflect resource cost. RTI endorsed short-term regression-based adjustments, but also concluded that more refined and accurate accounting data are the preferred long-term solution to mitigate charge compression and related bias in hospital cost-based weights. For a more detailed summary of RTI's findings, recommendations, and public comments we received on the report, we refer readers to the FY 2009 IPPS final rule (73 FR 48452 through 48453).

3. Summary of Policy Changes Made in FY 2011

In the FY 2009 IPPS/LTCH PPS final rule (73 FR 48458 through 48467), in response to the RTI's recommendations concerning cost report refinements, and because of RAND's finding that regression-based adjustments to the CCRs do not significantly improve payment accuracy, we discussed our decision to pursue changes to the cost report to split the cost center for Medical Supplies Charged to Patients into one line for "Medical Supplies Charged to Patients" and another line for "Implantable Devices Charged to Patients." (We refer readers to the Web site: *http://www.rand.org/pubs/working_papers/WR560/,* and the FY 2009 IPPS/LTCH PPS final rule for details on the RAND report (73 FR 48453 through 48457).) We acknowledged, as RTI had found, that charge compression occurs in several cost centers that exist on the Medicare cost report. However, as we stated in the FY 2009 IPPS/LTCH PPS final rule, we focused on the CCR for Medical Supplies and Equipment because RTI found that the largest impact on the MS–DRG relative weights could result from correcting charge compression for devices and implants. In determining what should be reported in these respective cost centers, we adopted the commenters' recommendation that hospitals should use revenue codes established by AHA's National Uniform Billing Committee to determine what should be reported in the "Medical Supplies Charged to Patients" and the "Implantable Devices Charged to Patients" cost centers. Accordingly, a new subscripted line 55.30 for "Implantable Devices Charged to Patients" was created in July 2009 as part of CMS' Transmittal 20 update to the existing cost report Form CMS–2552–96. This new subscripted cost center has been available for use for cost reporting periods beginning on or after May 1, 2009.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create standard cost centers for CT scans, MRI, and cardiac catheterization, and to require that hospitals report the costs and charges for these services under new cost centers on the revised Medicare cost report Form CMS 2552–10. As we discussed in the FY 2009 IPPS/LTCH PPS and CY 2009 OPPS/ASC proposed and final rules, RTI found that the costs and charges of CT scans, MRI, and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI also concluded that both the IPPS and OPPS relative weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRI, 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, MRI, and cardiac catheterization.) The new standard cost centers for MRI, CT scans, and cardiac catheterization are effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10. CMS issued the new hospital cost report Form CMS–2552–10 on December 30, 2010. The new cost report form can be accessed at the CMS Web site at: *https://www.cms.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS021935&intNumPerPage=10*. Once at this Web site, users should double click on "Chapter 40."

4. Discussion for FY 2012

In the FY 2009 IPPS/LTCH PPS final rule (73 FR 48468), we stated that, due to what is typically a 3-year lag between the reporting of cost report data and the availability for use in ratesetting, we anticipated that we might be able to use data from the new "Implantable Devices Charged to Patients" cost center to develop a CCR for Implantable Devices Charged to Patients in the FY 2012 or FY 2013 IPPS rulemaking cycle. Specifically, we stated, "Because there is approximately a 3-year lag between the availability of cost report data for IPPS and OPPS rate-setting purposes in a given fiscal year, we may be able to derive two distinct CCRs, one for medical supplies and one for devices, for use in calculating the FY 2012 or FY 2013 IPPS relative weights and the CY 2012 or CY 2013 OPPS relative weights" (73 FR 48468). However, as noted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43782), due to delays in the issuance of the revised cost report CMS 2552–10,

a new CCR for Implantable Devices Charged to Patients may not be available until FY 2013. Similarly, when we finalized the decision in the FY 2011 IPPS/LTCH PPS final rule to add new cost centers for MRI, CT scans, and cardiac catheterization, we explained that data from any new cost centers that may be created will not be available until at least 3 years after they are first used (75 FR 50077). That is, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50077), we stated that the data from the standard cost centers for MRI, CT scans, and cardiac catheterization, respectively, would not even be available for possible use in calculating the relative weights earlier than 3 years after Form CMS–2552–10 becomes available. We further stated that, at that time, we would analyze the data and determine if it is appropriate to use those data to create distinct CCRs from these cost centers for use in the relative weights for the respective payment systems. We also reassured public commenters that there was no need for immediate concern regarding possible negative payment impacts on MRI and CT scans under the IPPS and the OPPS because the cost report data that would be used for the calculation of the relative weights were at least 3 years from being available. We stated that we will first thoroughly analyze and run impacts on the data and provide the public with the opportunity to comment before distinct CCRs for MRI and CT scans would be finalized for use in the calculation of the relative weights. We also urged all hospitals to properly report their costs and charges for MRI, CT scans, and all other services so that, in several years' time, we will have reliable data from all hospitals on which to base a decision as to whether to incorporate additional CCRs into the relative weight calculation (75 FR 50077).

Accordingly, in preparation for this FY 2012 IPPS/LTCH PPS proposed rule, we have assessed the availability of data in the "Implantable Devices Charged to Patients" cost center. In order to develop a robust analysis regarding the use of cost data from the "Implantable Devices Charged to Patients" cost center, it is necessary to have a critical mass of cost reports filed with data in this cost center. The cost center for "Implantable Devices Charged to Patients" is effective for cost reporting periods beginning on or after May 1, 2009. We have checked the availability of FY 2009 cost reports in the December 31, 2010 quarter ending update of HCRIS, which is the latest upload of FY 2009 cost report data that we could use for this proposed rule. We have determined that there are only 437 hospitals (out of approximately 3,500 IPPS hospitals) that have completed the "Implantable Devices Charged to Patients" cost center. We do not believe that this is a sufficient amount of data from which to generate a meaningful analysis in this particular situation. Therefore, we are not proposing to use data from the "Implantable Devices Charged to Patients" cost center to create a distinct CCR for Implantable Devised Charged to Patients for use in calculating the MS–DRG relative weights for FY 2012. We will reassess the availability of data for the "Implantable Devices Charged to Patients" cost center, and the "MRI, CT Scans, and Cardiac Catheterization" cost centers, for the FY 2013 IPPS rulemaking cycle and, if appropriate, we will propose to create a distinct CCR at that time.

F. Preventable Hospital-Acquired Conditions (HACs), Including Infections

1. Background

a. Statutory Authority

Section 1886(d)(4)(D) of the Act addresses certain hospital-acquired conditions (HACs), including infections. Section 1886(d)(4)(D) of the Act specifies that by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) Are high cost, high volume, or both; (b) are assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with CDC, from time to time as long as the list contains at least two conditions.

Section 1886(d)(4)(D)(iii) of the Act requires that hospitals, effective with discharges occurring on or after October 1, 2007, submit information on Medicare claims specifying whether diagnoses were present on admission (POA). Section 1886(d)(4)(D)(i) of the Act specifies that effective for discharges occurring on or after October 1, 2008, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS–DRG if a selected condition is not POA. Thus, if a selected condition that was not POA manifests during the hospital stay, it is considered a HAC and the case is paid as though the secondary diagnosis was not present. However, even if a HAC manifests during the hospital stay, if any nonselected CC/MCC appears on the claim, the claim will be paid at the higher MS–DRG rate. Under the HAC payment policy, all CCs/MCCs on the claim must be HACs in order to generate a lower MS–DRG payment. In addition, Medicare continues to assign a discharge to a higher paying MS–DRG if a selected condition is POA.

The POA indicator reporting requirement and the HAC payment provision apply to IPPS hospitals only. Non-IPPS hospitals, including CAHs, LTCHs, IRFs, IPFs, cancer hospitals, children's hospitals, hospitals in Maryland operating under waivers, rural health clinics, federally qualified health centers, RNHCIs, and Department of Veterans Affairs/Department of Defense hospitals, are exempt from POA reporting and the HAC payment provision. Throughout this section, the term "hospital" refers to an IPPS hospital.

The HAC provision found in section 1886(d)(4)(D) of the Act is part of an array of Medicare value-based purchasing (VBP) tools that we are using to promote increased quality and efficiency of care. Those tools include measuring performance, using payment incentives, publicly reporting performance results, applying national and local coverage policy decisions, enforcing conditions of participation, and providing direct support for providers through Quality Improvement Organization (QIO) activities. The application of VBP tools, such as this HAC provision, is transforming Medicare from a passive payer to an active purchaser of higher value health care services. We are applying these strategies for inpatient hospital care and across the continuum of care for Medicare beneficiaries.

These VBP tools are highly compatible with the underlying purposes as well as existing structural features of Medicare's IPPS. Under the IPPS, hospitals are encouraged to treat patients efficiently because they receive the same DRG payment for stays that vary in length and in the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, conditions acquired in the hospital do not generate higher payments than the hospital would otherwise receive for cases without these conditions. To this extent, the IPPS encourages hospitals to avoid complications.

However, the treatment of certain conditions can generate higher Medicare payments in two ways. First, if a hospital incurs exceptionally high costs treating a patient, the hospital stay may

generate an outlier payment. Because the outlier payment methodology requires that hospitals experience large losses on outlier cases before outlier payments are made, hospitals have an incentive to prevent outliers. Second, under the MS–DRG system that took effect in FY 2008 and that has been refined through rulemaking in subsequent years, certain conditions can generate higher payments even if the outlier payment requirements are not met. Under the MS–DRG system, there are currently 259 sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or an MCC. The presence of a CC or an MCC generally results in a higher payment. However, since we implemented the HAC provisions, if a secondary diagnosis acquired during a hospital stay is a HAC and no other CCs or MCCs are present, the hospital receives a payment under the MS–DRGs as if the HACs were not present. (We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a discussion of DRG reforms (72 FR 47141).)

b. HAC Selection

Beginning in FY 2007, we have proposed, solicited, and responded to public comments and have implemented section 1886(d)(4)(D) of the Act through the IPPS annual rulemaking process. For specific policies addressed in each rulemaking cycle, we direct readers to the following publications: the FY 2007 IPPS proposed rule (71 FR 24100) and final rule (71 FR 48051 through 48053); the FY 2008 IPPS proposed rule (72 FR 24716 through 24726) and final rule with comment period (72 FR 47200 through 47218); the FY 2009 IPPS proposed rule (73 FR 23547) and final rule (73 FR 48471); the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43782); and the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23880) and final rule (75 FR 50080). A complete list of the 10 current categories of HACs is included in section II.F.2. of this preamble.

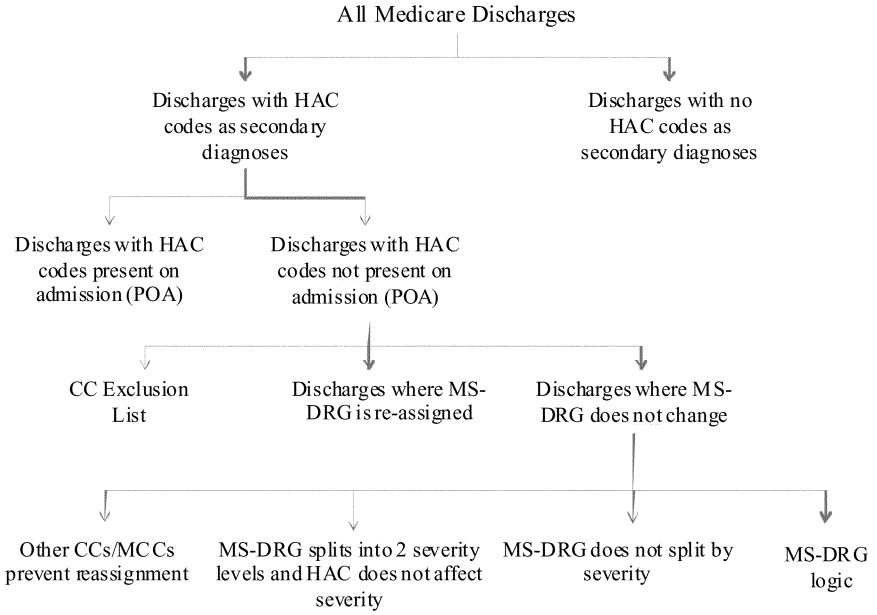
In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50080 through 50101), we did not add any additional HACs or make any changes to policies already established under the authority of section 1886(d)(4)(D) of the Act.

c. Collaborative Process

In establishing the HAC payment policy under section 1886(d)(4)(D) of the Act, our experts have worked closely with public health and infectious disease professionals from across the Department of Health and Human Services, including CDC, the Agency for Healthcare Research and Quality (AHRQ), and the Office of Public Health and Science (OPHS), to identify the candidate preventable HACs, review comments, and select HACs. CMS and CDC also have collaborated on the process for hospitals to submit a POA indicator for each diagnosis listed on IPPS hospital Medicare claims and on the payment implications of the various POA reporting options. In addition, as discussed below, we have used rulemaking and Listening Sessions to obtain public input.

d. Application of HAC Payment Policy to MS–DRG Classifications

As described above, in certain cases, application of the HAC payment policy provisions can result in MS–DRG reassignment to a lower paying MS–DRG. The following diagram portrays the logic of the HAC payment policy provision as adopted in the FY 2008 IPPS final rule with comment period (72 FR 47200) and in the FY 2009 IPPS final rule (73 FR 48471):



e. Public Input Regarding Selected and Potential Candidate HACs

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50080 through 50101), we did not add or remove categories of HACs, nor did we make any changes to previously established policies. However, we continue to encourage public dialogue about refinement of the HAC list.

Given the timeliness of the HAC discussion, particularly when considered within the context of recent legislative health care reform initiatives, we remain eager to engage in an ongoing public dialogue about the various aspects of this policy. We plan to continue to include updates and findings from the RTI evaluation on CMS' Hospital-Acquired Conditions and Present on Admission Indicator Web site available at: *http://www.cms.hhs.gov/HospitalAcqCond/.*

f. POA Indicator Reporting

Collection of POA indicator data is necessary to identify which conditions were acquired during hospitalization for the HAC payment provision as well as for broader public health uses of Medicare data. In the FY 2011 IPPS/LTCH PPS proposed rule, we listed the instructions and change requests that were issued to IPPS hospitals and also to non-IPPS hospitals regarding the submission of POA indicator data for all diagnosis codes on Medicare claims and the processing of non-PPS claims (75 FR 23381). We also indicated that specific instructions on how to select the correct POA indicator for each diagnosis code were included in the *ICD–9–CM Official Guidelines for Coding and Reporting,* available on the CDC Web site at: *http://www.cdc.gov/nchs/data/icd9/icdguide10.pdf.* We reiterate that additional information regarding POA indicator reporting and application of the POA reporting options is available on the CMS Web site at: *http://www.cms.gov/HospitalAcqCond/.*

Historically, we have not provided coding advice. Rather, we collaborate with the American Hospital Association (AHA) through the *Coding Clinic for ICD–9–CM.* We will continue to collaborate with the AHA to promote the *Coding Clinic for ICD–9–CM* as the source for coding advice about the POA indicator.

As discussed in previous IPPS proposed and final rules, there are five POA indicator reporting options, as defined by the *ICD–9–CM Official Guidelines for Coding and Reporting:*

Indicator	Descriptor
Y	Indicates that the condition was present on admission.
W	Affirms that the hospital has determined that, based on data and clinical judgment, it is not possible to document when the onset of the condition occurred.
N	Indicates that the condition was not present on admission.
U	Indicates that the documentation is insufficient to determine if the condition was present at the time of admission.
1	Signifies exemption from POA reporting. CMS established this code as a workaround to blank reporting on the electronic 4010A1. A list of exempt ICD-9-CM diagnosis codes is available in the ICD-9-CM Official Guidelines for Coding and Reporting.

In the FY 2009 IPPS final rule (73 FR 48486 through 48487), we adopted final payment policies to: (1) Pay the CC/MCC MS–DRGs for those HACs coded with "Y" and "W" indicators; and (2) not pay the CC/MCC MS–DRGs for those HACs coded with "N" and "U" indicators.

Beginning on or after January 1, 2011, hospitals are required to begin reporting POA indicators using the 5010 electronic transmittal standards format. The 5010 format removes the need to report a POA indicator of "1" for codes that are exempt from POA reporting. However, for claims that continue to be submitted using the 4010 electronic transmittal standards format, the POA indicator of "1" is still necessary because of reporting restrictions from the use of the 4010 electronic transmittal standards format.

Hospitals that began reporting with the 5010 format on and after January 1, 2011, can no longer report a POA indicator of "1" for POA exempt codes. The POA field should instead be left blank for codes exempt from POA reporting. We have issued CMS instructions on this reporting change as a One-Time Notification, Pub. No. 100–20, Transmittal No. 756, Change Request 7024, effective on August 13, 2010. These instructions, entitled *5010 Implementation-Changes to Present on Admission (POA) Indicator "1" and the K3 Segment,* can be located at the following link on the CMS Web site: *http://www.cms.gov/manuals/downloads/Pub100_20.pdf.*

We are continuing our efforts to clarify instructions regarding use of the POA indicator. As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50088), we received public comments in response to the FY 2011 IPPS/LTCH PPS proposed rule that expressed concern about the accuracy of reporting of POA indicators for HACs related to intracranial injury with loss of consciousness. The codes for loss of consciousness are listed in the Falls and Trauma HAC category, within the "Intracranial Injury" subcategory. Because loss of consciousness is a component of intracranial injuries rather than a separate condition, we agreed that the POA guidelines that instructed coders to assign an "N" indicator if any part of the combination code was not present on admission did not apply to the loss of consciousness codes. As a member of the Editorial Advisory Board for the *Coding Clinic for ICD–9–CM,* we worked with the American Hospital Association (AHA), American Health Information Management Association (AHIMA), and the Centers for Disease Control and Prevention (CDC) to provide additional clarification on how these conditions should be reported. Additional guidance on how these cases should be reported can be found in AHA's *Coding Clinic for ICD–9–CM,* 2nd Quarter 2010, "Frequently Asked POA Questions" section. That publication clarified the POA reporting for patients in whom a single code captures the fact that the patient was admitted as a result of a head injury and then subsequently lost consciousness after the admission. For these cases, we clarified that the POA indicator assigned should be "Y," indicating that the head injury and resulting loss of consciousness occurred prior to (and was present on) admission.

We expect that this clarification will lead to greater consistency and accuracy in POA indicator reporting for these conditions. We look forward to continuing our efforts as part of the AHA's Editorial Advisory Board for *Coding Clinic for ICD–9–CM* to provide guidance on accuracy of coding and the reporting of POA indicators. Hospitals look to this publication to provide detailed guidance on ICD–9–CM coding and POA reporting. We encourage

hospitals to send any other questions about ICD–9–CM codes or POA indicator selection to the AHA so that the Editorial Advisory Board can continue its role of providing instruction on the accurate selection and reporting of both ICD–9–CM codes and POA indicators.

2. Proposed Additions and Revisions to the HAC Policy for FY 2012

a. Contrast-Induced Acute Kidney Injury

We discuss below our analysis for a proposed new condition as a possible candidate for selection for FY 2012 under section 1886(d)(4)(D) of the Act. As described in more detail in section II.F.1.a. of this preamble, each HAC must be: (1) High cost, high volume, or both; (2) assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and (3) could reasonably have been prevented through the application of evidence-based guidelines. We also discuss other considerations relating to the selection of a HAC, including any administrative or operational issues associated with a proposed condition. For example, the condition may only be able to be identified by multiple codes, thereby requiring the development of special GROUPER logic to also exclude similar or related ICD–9–CM codes from being classified as a CC or an MCC. Similarly, a condition acquired during a hospital stay may arise from another condition that the patient had prior to admission, making it difficult to determine whether the condition was reasonably preventable. We invite public comment on clinical, coding, and prevention issues on our proposal to add contrast-induced acute kidney injury as a condition subject to the HAC payment provision for FY 2012 (for discharges occurring on or after October 1, 2011).

Contrast-induced acute kidney injury is a significant complication of the use of iodinated contrast media and accounts for a large number of cases of hospital-acquired acute kidney injury cases. A published study has shown that renal failure associated with contrast administration is correlated with up to 11 percent of cases of renal failure that occur in hospitals (Nash, *et al.:* American Journal on Kidney Disease, 2002, Vol. 39, pp. 930–936). Patients who experience acute kidney injury have an increased risk of inhospital mortality even after adjustments for disease comorbidities (McCullough, J.: American College of Cardiology, 2008, pp. 1419 through 1428). Data suggest that the risk for mortality extends beyond the period of hospitalization, resulting in 1-year and 5-year mortality rates significantly higher than those patients who have not developed acute kidney injury. In addition, contrast-induced acute kidney injury is associated with an increased incidence of myocardial infarction, bleeding requiring transfusion, and prolonged hospital stays (McCullough, J.: American Journal of Medicine, 1997, Vol. 103, pp. 368 through 375). We note that "acute kidney injury" is a new terminology endorsed by the National Kidney Foundation to replace "acute renal failure."

There is not a unique code that identifies kidney injury. However, kidney injury can be identified as a subset of discharges with ICD–9–CM diagnosis code 584.9 (Acute kidney failure, unspecified). Our clinical advisors believe that diagnosis code 584.9, in combination with the associated procedure codes below, can accurately identify contrast-induced acute kidney injury:

- 88.40 (Arteriography using contrast material, unspecified site)
- 88.41 (Arteriography of cerebral arteries)
- 88.42 (Aortography)
- 88.43 (Arteriography of pulmonary arteries)
- 88.44 (Arteriography of other intrathoracic vessels)
- 88.45 (Arteriography of renal arteries)
- 88.46 (Arteriography of placenta)
- 88.47 (Arteriography of other intra-abdominal arteries)
- 88.48 (Arteriography of femoral and other lower extremity arteries)
- 88.49 (Arteriography of other specified sites)
- 88.50 (Angiocardiography, not otherwise specified)
- 88.51 (Angiocardiography of venae cavae)
- 88.52 (Angiocardiography of right heart structures)
- 88.53 (Angiocardiography of left heart structures)
- 88.54 (Combined right and left heart angiocardiography)
- 88.55 (Coronary arteriography using a single catheter)
- 88.56 (Coronary arteriography using two catheters)
- 88.57 (Other and unspecified coronary arteriography)
- 88.58 (Negative-contrast cardiac roentgenography)
- 88.59 (Intra-operative coronary fluorescence vascular angiography)
- 88.60 (Phlebography using contrast material, unspecified site)
- 88.61 (Phlebography of veins of head and neck using contrast material)
- 88.62 (Phlebography of pulmonary veins using contrast material)
- 88.63 (Phlebography of other intrathoracic veins using contrast material)
- 88.64 (Phlebography of the portal venous system using contrast material)
- 88.65 (Phlebography of other intra-abdominal veins using contrast material)
- 88.66 (Phlebography of femoral and other lower extremity veins using contrast material)
- 88.67 (Phlebography of other specified sites using contrast material)
- 87.71 (C.A.T. of kidney)
- 87.72 (Other nephrotomogram)
- 87.73 (Intravenous pyelogram)
- 87.74 (Retrograde pyelogram)
- 87.75 (Percutaneous pyelogram)

We are proposing to identify contrast-induced acute kidney injury with diagnosis code 584.9 in combination with one or more of the above associated procedure codes.

We also considered identifying contrast-induced acute kidney injury through the use of external injury codes, or E-codes. Code E947.8 (Other drugs and medicinal substances) has an inclusion term "Contrast media used for diagnostic x-ray procedures" to identify the use of contrast. However, we note that we do not currently require the reporting of E-codes for the HAC payment provisions under the IPPS. Therefore, we would be unable to rely on the identification of contrast-induced acute kidney injury through E-codes on Medicare IPPS HAC claims.

Section 1886(d)(4)(D) of the Act requires that a HAC be a condition that is "high cost, high volume, or both." In FY 2009, there were 38,324 inpatient discharges coded with acute renal failure as specified by ICD–9–CM diagnosis code 584.9 reported as not present on admission (POA status = N) when reported with one of the above procedure codes submitted through Medicare claims. The cases had an average charge of $29,122 for the entire hospital stay. Studies suggest the additional average cost per day for a patient who has acquired contrast-induced acute kidney injury is $2,654. Other data report patients stays increases by 3.75 days once they have acquired the diagnosis (Subramanian, *et al.: Journal of Medical Economics,* 2007, Vol. 10, pp. 119 through 134).

There are widely recognized guidelines for the prevention of acute kidney injury that address the prevention of contrast-induced acute kidney injury, and we believe the condition is reasonably preventable. One of these guidelines can be found at: *http://www.renal.org/Clinical/*

GuidelineSection/AcuteKidneyInjury.aspx.

The condition of contrast-induced acute kidney injury as specified in our proposal is a CC under the MS DRGs.

We have not identified any additional administrative or operational difficulties with proposing this condition as a HAC. We invite public comment on whether contrast-induced acute kidney injury meets the requirements set forth under section 1886(d)(4)(D) of the Act, as well as other coding and prevention issues associated with our proposal to add this injury as a condition subject to the HAC payment provision for FY 2012 (for discharges occurring on or after October 1, 2011). We are particularly interested in receiving comments on the degree to which contrast-induced acute kidney injury is reasonably preventable through the application of evidence-based guidelines.

b. New Diagnosis Codes Proposed to be Added to Existing HACs

As changes to diagnosis codes and new diagnosis codes are proposed and finalized for the list of CCs and MCCs, we modify the list of selected HACs to reflect these changes. Included in Table 6A, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, are five new ICD–9–CM diagnosis codes that we are proposing to add to three of the current HAC categories. We are proposing to add two new codes for the Falls and Trauma HAC category, two new codes for the Surgical Site Infection (SSI) Following Certain Bariatric Procedures HAC category, and one new code for the Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category. The two new diagnosis codes that we are proposing to add to the Falls and Trauma HAC category are code 808.44 (Multiple closed pelvic fractures without disruption of pelvic circle) and code 808.54 (Multiple open pelvic fractures without disruption of pelvic circle). These codes fall within the range of the fracture code subcategory (800 through 829). The two new diagnosis codes that we are proposing to add to the Surgical Site Infection (SSI) Following Certain Bariatric Procedures HAC category are code 539.01 (Infection due to gastric band procedure) and code 539.81 (Infection due to other bariatric procedure). We believe these diagnosis codes are appropriate for inclusion in the existing category when reported as a secondary diagnosis with the specified principal diagnosis code of morbid obesity (code 278.01) and one of the designated bariatric procedure codes (code 44.38, 44.39, or 44.95). Lastly, the one new diagnosis code that we are proposing to add to the Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category is code 415.13 (Saddle embolus of pulmonary artery). Diagnosis code 415.13 would be applicable when reported along with one of the following procedures codes describing certain orthopedic procedures: 00.85 through 00.87, 81.51, 81.52, or 81.54. Shown in the table below are these five new diagnosis codes with their corresponding descriptions and their proposed CC/MCC designations.

ICD-9-CM Code	Code Descriptor	Proposed CC/MCC Designation
539.01	Infection due to gastric band procedure	CC
539.81	Infection due to other bariatric procedure	CC
415.13	Saddle embolus of pulmonary artery	MCC
808.44	Multiple closed pelvic fractures without disruption of pelvic circle	CC
808.54	Multiple open pelvic fractures without disruption of pelvic circle	MCC

We are inviting public comments on the proposed adoption of theses five new ICD–9–CM diagnosis codes as CC/MCCs that are listed above, which, if finalized, would be added to the current Falls and Trauma HAC category, Surgical Site Infection (SSI) Following Certain Bariatric Procedures HAC category and Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Following Certain Orthopedic Procedures HAC category and would be subject to the HAC payment provision for FY 2012.

c. Revision to HAC Subcategory Title

After publication of the FY 2011 IPPS/LTCH PPS final rule, we received a comment stating that the subcategory title "Electric Shock" that is included in the Falls and Trauma HAC category was misleading. The commenter stated that this subcategory title did not accurately describe the CC/MCC ICD–9–CM diagnoses codes (991 through 994) contained within this subcategory. The commenter requested that CMS develop a new title that would more accurately describe this group of codes.

We agree with the commenter that the HAC subcategory title "Electric Shock" is potentially misleading because the codes included within these ranges contain a variety of injuries, including the following:

- Category 991 (Effects of Reduced Temperature)
- Category 992 (Effects of Heat and Light)
- Category 993 (Effects of Air Pressure)
- Category 994 (Effects of Other External Causes)

We are proposing to change the title of this HAC subcategory from "Electric Shock" to "Other Injuries" because it includes a variety of injury codes. The subcategory will continue to include the codes within the 991–994 code ranges appearing on the CC/MCC list. We are proposing no changes to the list of codes in this subcategory; we are simply proposing to rename the subcategory title. We invite public comments on this proposed title change to the HAC subcategory from "Electric Shock" to "Other Injuries" for FY 2012.

d. Conclusion

The following table lists the current HAC categories and the ICD–9–CM codes that identify the conditions and have been finalized through FY 2011. For FY 2012, we are proposing that these conditions continue to be subject to the HAC payment provision, along with the creation of a new HAC category for Contrast-Induced Acute Kidney Injury as discussed in section II.F.2.a. of this preamble. In addition, we are proposing to add five new ICD–9–CM diagnosis codes and to revise the title of the "Electric Shock" subcategory in the Falls and Trauma HAC category.

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HAC	CC/MCC (ICD-9-CM Code)
Foreign Object Retained After Surgery	998.4 (CC) 998.7 (CC)
Air Embolism	999.1 (MCC)
Blood Incompatibility	999.60 (CC) 999.61 (CC) 999.62 (CC) 999.63 (CC) 999.69 (CC)
Pressure Ulcer Stages III & IV	707.23 (MCC) 707.24 (MCC)
Falls and Trauma: - Fracture - Dislocation - Intracranial Injury - Crushing Injury - Burn - Electric Shock	Codes within these ranges on the CC/MCC list: 800-829 830-839 850-854 925-929 940-949 991-994
Catheter-Associated Urinary Tract Infection (UTI)	996.64 (CC) Also excludes the following from acting as a CC/MCC: 112.2 (CC) 590.10 (CC) 590.11 (MCC) 590.2 (MCC) 590.3 (CC) 590.80 (CC) 590.81 (CC) 595.0 (CC) 597.0 (CC) 599.0 (CC)
Vascular Catheter-Associated Infection	999.31 (CC)
Manifestations of Poor Glycemic Control	250.10-250.13 (MCC) 250.20-250.23 (MCC) 251.0 (CC) 249.10-249.11 (MCC) 249.20-249.21 (MCC)
Surgical Site Infections	
Surgical Site Infection, Mediastinitis, Following Coronary Artery Bypass Graft (CABG)	519.2 (MCC) And one of the following procedure codes: 36.10–36.19

Surgical Site Infection Following Certain Orthopedic Procedures	996.67 (CC) 998.59 (CC) And one of the following procedure codes: 81.01-81.08, 81.23-81.24, 81.31-81.38, 81.83, 81.85
Surgical Site Infection Following Bariatric Surgery for Obesity	*Principal Diagnosis* – 278.01 998.59 (CC) And one of the following procedure codes: 44.38, 44.39, or 44.95
Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures	415.11 (MCC) 415.19 (MCC) 453.40-453.42 (CC) And one of the following procedure codes: 00.85-00.87, 81.51-81.52, or 81.54

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We refer readers to section II.F.6. of the FY 2008 IPPS final rule with comment period (72 FR 47202 through 47218) and to section II.F.7. of the FY 2009 IPPS final rule (73 FR 48474 through 48486) for detailed analyses supporting the selection of each of the HACs selected through FY 2011.

3. RTI Program Evaluation Summary

a. Background

On September 30, 2009, a contract was awarded to Research Triangle Incorporated (RTI) to evaluate the impact of the Hospital-Acquired Condition-Present on Admission (HAC–POA) provisions on the changes in the incidence of selected conditions, effects on Medicare payments, impacts on coding accuracy, unintended consequences, and infection and event rates. This is an intra-agency project with funding and technical support coming from CMS, OPHS, AHRQ, and CDC. The evaluation will also examine the implementation of the program and evaluate additional conditions for future selection.

RTI's evaluation of the HAC–POA provisions is divided into several parts. In the FY 2011 IPPS/LTCH PPS final rule (50085 through 50101), we summarized the analyses by RTI that had been completed at that time. These RTI analyses of POA indicator reporting, frequencies and net savings associated with current HACs, and frequencies of previously considered candidate HACs reflected MedPAR claims from October 2008 through September 2009.

b. FY 2009 Data Analysis

As we describe above, we have provided instructions to IPPS hospitals and non-IPPS hospitals regarding the submission of POA indicator data for all diagnosis codes on Medicare claims and the processing of non-PPS claims (75 FR 23381) and note that specific instructions on how to select the correct POA indicator for each diagnosis code were included in the *ICD–9–CM Official Guidelines for Coding and Reporting,* available on the CDC Web site at: *http://www.cdc.gov/nchs/data/icd9/icdguide10.pdf.* After publication of the FY 2011 IPPS/LTCH PPS final rule, we identified a discrepancy between the claims data that hospitals submitted and the CMS data file used to calculate the HAC measures. Specifically, this error led to incorrect HAC assignments in cases where a hospital reported an external cause of injury (E-code). Since then, we have corrected this error in the data file.

As a result, the RTI analysis of the HAC–POA program that was conducted using FY 2009 claims data will be updated using the corrected data file. We do not expect the corrected data to have a material impact on our previous findings for FY 2009. Revised data tables will be made publicly available on the CMS Web site at *http://www.cms.gov/HospitalAcqCond/01_Overview.asp* and the RTI Web site at *http://www.rti.org/reports/cms/* soon after publication of this proposed rule.

c. FY 2010 Data Analysis

RTIs analysis of the FY 2010 MedPAR data file for the HAC–POA program evaluation was not fully complete in time for publication in this proposed rule. We will provide the results from the study on the CMS Web site at *http://www.cms.gov/HospitalAcqCond/01_Overview.asp* and on the RTI Web site at *http://www.rti.org/reports/cms/* when available. We anticipate that the examination of FY 2010 MedPAR data will be completed soon after publication of this proposed rule. We invite public comment on RTI's analysis of the FY 2010 MedPAR data for the HAC–POA program.

G. Proposed Changes to Specific MS–DRG Classifications

In this proposed rule, we are inviting public comment on each of the MS–DRG classification proposed changes described below, as well as our proposals to maintain certain existing MS–DRG classifications, which are also discussed below. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data. In other cases, we are proposing to maintain the existing MS–DRG classification based on our analysis of claims data.

1. Pre-Major Diagnostic Categories (Pre-MDCs)

a. Noninvasive Mechanical Ventilation

We received a request from the National Association for Medical Direction of Respiratory Care (NAMDRC) which suggested that we

create a new MS–DRG for patients with certain respiratory conditions who receive noninvasive mechanical ventilation (NIV). The requestor stated that patients who receive NIV are almost always placed within an intensive care unit (ICU) or an emergency department and use the resources available in those areas. The requestor recommended that this new MS–DRG recognize current practice and allow for appropriate reimbursement for the technical complexity and monitoring required for NIV as a form of acute life support. According to the requestor, NIV has evolved to become first-line supportive therapy for several forms of acute respiratory failure. Lastly, the requestor recommended that the new MS–DRG identify NIV usage of approximately 6 to 12 hours to account for the "legitimate but very short term use of this therapy."

Historically, the concept of mechanical ventilation for critically ill patients included establishment of an artificial airway, invasively, through endotracheal intubation or a tracheostomy. According to the requestor, a significant portion of these patients can now be treated through noninvasive mechanical ventilation with the use of a face or nasal mask. In the ICD–9–CM classification system, NIV is described by procedure code 93.90 (Noninvasive mechanical ventilation), while invasive mechanical ventilation is described by procedure codes 96.70 (Continuous invasive mechanical ventilation of unspecified duration), 96.71 (Continuous invasive mechanical ventilation for less than 96 consecutive hours), and 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more). The requestor submitted external data to illustrate trends in NIV use over the past decade. These data were derived from a survey conducted during 2002–2003 of several hospitals located in Massachusetts and Rhode Island. The requestor believed that these data indicate patients with exacerbation of chronic obstructive pulmonary disease (COPD), acute pulmonary edema, or worsening congestive heart failure are successfully managed with NIV.

We analyzed FY 2010 MedPAR claims data that are representative of the respiratory conditions the requestor identified when reported with NIV. We found 14 MS–DRGs reporting procedure code 93.90 using the above specifications. The MS–DRGs are as follows:

Pre-MDC MS–DRGs:

- MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation 96+ Hrs or PDX Except Face, Mouth & Neck with Major O.R.)
- MS–DRG 004 (Tracheostomy with Mechanical Ventilation 96+ Hrs or PDX Except Face, Mouth & Neck without Major O.R.) MS–DRGs:
- MS–DRG 189 (Pulmonary Edema & Respiratory Failure)
- MS–DRG 190 (Chronic Obstructive Pulmonary Disease with MCC)
- MS–DRG 191 (Chronic Obstructive Pulmonary Disease with CC)
- MS–DRG 192 (Chronic Obstructive Pulmonary Disease without CC/MCC)
- MS–DRG 204 (Respiratory Signs & Symptoms)
- MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support 96+ Hours)
- MS–DRG 208 (Respiratory System Diagnosis with Ventilator Support <96 Hours)
- MS–DRG 222 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC)
- MS–DRG 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC)
- MS–DRG 291 (Heart Failure & Shock with MCC)
- MS–DRG 292 (Heart Failure & Shock with CC)
- MS–DRG 293 (Heart Failure & Shock without CC/MCC)

As shown in the list above and in the chart below, the MS–DRGs identified also include those that describe invasive mechanical ventilation. The ICD–9–CM coding convention instructs the reporting of both types of mechanical ventilation when patients are admitted on noninvasive mechanical ventilation that subsequently requires invasive mechanical ventilation therapy.

The data demonstrate that, in certain MS–DRGs, for example, MS–DRGs 003, 004, and 222 that the cases with NIV primarily have shorter lengths of stay and lower average costs compared to all the cases in those MS–DRGs. Alternatively, the data for MS–DRGs 189, 190, 191, and 192 demonstrate that the cases with NIV have an increased length of stay and higher average costs, but a relatively low volume compared to all the cases in those MS–DRGs. Combining the current surgical and medical MS–DRGs into a single, new MS–DRG would include noninvasive mechanical ventilation cases with a wide range of costs for several indications with varying levels of severity. The average costs for these cases range from a low of $5,794 in MS–DRG 293 to a high of $95,940 in MS–DRG 003. We believe the cases are more appropriately assigned and reimbursed in the MS–DRGs to which they are currently assigned.

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MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 003 – All cases	18,223	34.7	$103,492
MS-DRG 003 - Cases with code 93.90 without code 96.70, 96.71, or 96.72	58	33.3	$95,940
MS-DRG 004 – All cases	19,599	25.79	$63,022
MS-DRG 004 – Cases with code 93.90 without code 96.70, 96.71, or 96.72	170	25.43	$58,500
MS-DRG 189 – All cases	87,668	5.36	$8,317
MS-DRG 189 – Cases with code 93.90 without code 96.70, 96.71, or 96.72	22,023	6.07	$10,383
MS-DRG 190 – All cases	130,731	5.30	$7,140
MS-DRG 190 – Cases with code 93.90 without code 96.70, 96.71 or 96.72	8,450	6.78	$11,207
MS-DRG 191 – All cases	135,851	4.49	$6,236
MS-DRG 191 – Cases with code 93.90 without code 96.70, 96.71 or 96.72	4,563	5.41	$8,819
MS-DRG 192 – All cases	115,153	3.52	$4,621
MS-DRG 192 – Cases with code 93.90 without code 96.70, 96.71 or 96.72	2,334	4.25	$6,803
MS-DRG 204 – All cases	21,049	2.61	$4,310
MS-DRG 204 – Cases with code 93.90 without code 96.70, 96.71 or 96.72	265	4.17	$7,591
MS-DRG 207 – All cases	32,752	14.61	$32,897
MS-DRG 207 – Cases with code 93.90 without code 96.70, 96.71 or 96.72	0	0	0
MS-DRG 208 – All cases	67,724	6.98	$14,742
MS-DRG 208 – Cases with code 93.90 without code 96.70, 96.71 or 96.72	0	0	0
MS-DRG 222 – All cases	2,279	11.98	$57,478
MS-DRG 222 – Cases with code 93.90 without code 96.70, 96.71 or 96.72	52	11.79	$55,011
MS-DRG 223 – All cases	3,230	6.17	$41,754
MS-DRG 223 – Cases with code 93.90 without code 96.70, 96.71 or 96.72	19	11.05	$47,064
MS-DRG 291 – All cases	170,399	6.05	$9,585
MS-DRG 291 – Cases with code 93.90 without code 96.70, 96.71 or 96.72	14,274	6.95	$12,320
MS-DRG 292 – All cases	220,031	4.72	$6,584
MS-DRG 292 – Cases with code 93.90 without code 96.70, 96.71 or 96.72	5,171	5.58	$9,180
MS-DRG 293 – All cases	98,134	3.20	$4,410
MS-DRG 293 – Cases with code 93.90 without code 96.70, 96.71 or 96.72	1,381	3.43	$5,794

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As mentioned in the requestor's comments, and our clinical advisors agree, NIV encompasses a broad range of interventions and utilizes periods of time that range from a few hours to a few days of continuous chronic use. Resource requirements are vastly different for the various intended indications. For example, as also noted by the requestor, respiratory failure can have many forms. Our clinical advisors provided three subsets of patients as an example: Those that are given oxygen support, those that are given pressure (rate) support, and those that are intubated. There is overlap between the three subsets in that a patient may require one, two, or all three types of therapy and there are multiple options for any given patient. Our clinical advisors stated that these various subsets of patients can require significantly different resources. Lastly, respiratory failure reflects the severity of the diagnosis (it is a complication) while NIV is a therapeutic option. Unlike a major surgical intervention where the intervention creates morbidity, NIV merely reflects the severity of the underlying respiratory failure.

The requestor further noted in its comments that a significant number of patients who receive NIV fail this therapy and must be intubated and subsequently placed on a ventilator. However, those patients who require both noninvasive and invasive mechanical ventilation are already accounted for in the invasive mechanical ventilation MS–DRGs. Similar to patients with respiratory failure, patients with heart failure and shock have a comparable severity of illness where each condition reflects the severity of the diagnosis (it is a complication). Therefore, the cost is already reflected in the high resource expenditure estimates for MS–DRGs 222, 223, 291, 292, and 293, as are all other severity-correlated resource costs.

In conclusion, we believe that the data do not support the creation of a single MS–DRG to identify NIV cases. As stated previously, the average costs for the NIV cases range from a low of $5,794 in MS–DRG 293 to a high of $95,940 in MS–DRG 003. If created, this single MS–DRG would include patients with a wide range in average costs. We believe the cases are more appropriately captured in their current MS–DRGs. In addition to the clinical points raised by our clinical advisors and outlined above, the volume and length of stay data for cases where NIV was reported with the specified respiratory conditions further support their present MS–DRG assignments. Therefore, we are not proposing to create a new MS–DRG for patients receiving NIV. We invite public comment on our proposal not to create a new MS–DRG for patients receiving NIV for FY 2012.

b. Debridement With Mechanical Ventilation Greater Than 96 Hours With Major Operating Room (O.R.) Procedure

We received a comment concerning the use of excisional debridement in cases with complications that lead to the need for extended mechanical ventilation. The commenter stated that patients undergoing procedures such as excisional debridement may also develop extensive complications such as respiratory failure and sepsis. The commenter indicated that these patients tend to use significant resources. The commenter stated that these cases are currently assigned to MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support 96+ Hours) or MS–DRG 870 (Septicemia with or Severe Sepsis with Mechanical Ventilation 96+ Hours). The commenter expressed a concern that the operating room (OR) procedure of the excisional debridement was not fully recognized through either of these two medical MS–DRGs. The commenter requested that a new MS–DRG be created that would include mechanical ventilation of greater than 96 hours with the presence of an additional major OR procedure.

We agree that patients with long-term mechanical ventilation greater than 96 hours and a major OR procedure utilize extensive resources. However, we point out that these patient cases are not currently assigned to MS–DRG 207 or MS–DRG 870 as the commenter stated. Many of these long-term mechanical ventilation patient cases are instead assigned to MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation 96+ Hours or PDX, Excluding Face, Mouth & Neck with Major Operating Room Procedure). Cases that require mechanical ventilation for greater than 96 hours, that have a tracheostomy performed, and that have a procedure on the major O.R. list (including excisional debridement) are assigned to MS–DRG 003. We specifically created MS–DRG 003 to capture these complicated patients on long-term mechanical ventilation who also have a major O.R. procedure. Therefore, we are not proposing to create a second MS–DRG to capture these patients at this time. We welcome public comments on our proposal not to create a new MS–DRG for these patients for FY 2012.

c. Autologous Bone Marrow Transplant

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50101), effective October 1, 2011, we deleted MS–DRG 009 (Bone Marrow Transplant) and created two new MS–DRGs: MS–DRG 014 (Allogeneic Bone Marrow Transplant) and MS–DRG 015 (Autologous Bone Marrow Transplant). We created new MS–DRGs 014 and 015 because of differences in costs associated with these procedures. During the comment period for the FY 2011 IPPS/LTCH PPS proposed rule, two commenters who supported the proposed reclassification of the bone marrow transplant MS–DRGs requested further refinement to account for severity of illness. At that time, we did not subdivide MS–DRG 014 and MS–DRG 015 based on severity of illness because they did not meet our criteria for subdivision (75 FR 50102).

As we outlined in our FY 2008 IPPS/LTCH PPS final rule with comment period (72 FR 47169), in designating an MS–DRG as one that would be subdivided into subgroups based on the presence of a CC or an MCC, we developed a set of criteria to facilitate our decision-making process. The original criteria were based on average charges; we now use average costs (FY 2007 IPPS final rule, 71 FR 47882). In order to warrant creation of a CC or an MCC subgroup within a base MS–DRG, the subgroup must meet all of the following five criteria:

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

We examined FY 2010 MedPAR claims data for these newly created MS–DRGs, and based on these criteria, we identified MS–DRG 015 as a possible MS–DRG that would require further subdivision. MS–DRG 014 was not identified, as this MS–DRG did not meet the criteria stated above for possible subdivision. Autologous bone marrow transplantation utilizes the patient's own bone marrow or stem cells in the treatment of certain cancers and bone marrow diseases. These procedures restore stem cells that have been destroyed either by chemotherapy and/or radiation treatment.

In our analysis, we found 1,338 total cases assigned to MS–DRG 015 with average costs of approximately $38,608

and an average length of stay of approximately 18.8 days. There were 1,092 cases that had a secondary diagnosis code reported on the claim that was designated as a CC or an MCC with average costs of approximately $40,974 and an average length of stay of approximately 19.7 days. There were 246 cases without a secondary diagnosis code reported on the claim that had a CC or an MCC designation with average cost of approximately $28,105 and an average length of stay of approximately 14.6 days. The following table illustrates our findings:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 015 - All cases	1,338	18.8	$38,608
MS-DRG 015 - Cases with MCC/CC	1,092	19.7	$40,974
MS-DRG 015 - Cases without MCC/CC	246	14.6	$28,105

We found that the cases reported with a secondary diagnosis code of a CC or an MCC were more costly and had a longer average length of stay than both the overall cases assigned to MS–DRG 015 and the cases without a CC or an MCC. The cases without a CC or an MCC were less costly and had a shorter average length of stay than both the cases with a CC or an MCC and the overall cases assigned to that MS–DRG. Based on our analysis, all five criteria for a subgroup division were met, thereby supporting a 2-level severity split for MS–DRG 015. Therefore, we are proposing to delete MS–DRG 015 and create two new MS–DRGs:

- Proposed MS–DRG 016 (Autologous Bone Marrow Transplant with MCC/CC); and
- Proposed MS–DRG 017 (Autologous Bone Marrow Transplant without MCC/CC).

We invite public comment on our proposal to delete MS–DRG 015 and create two new MS–DRGs 016 and 017 for autologous bone marrow transplant for FY 2012.

2. MDC 1 (Diseases and Disorders of the Nervous System): Rechargeable Dual Array Deep Brain Stimulation System

We received a public comment in response to the FY 2011 IPPS/LTCH PPS proposed rule regarding the MS–DRG assignment for rechargeable dual array deep brain neurostimulators. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50128), we indicated that we considered this comment outside of the scope of the proposed rule as we did not propose any changes for these procedures for FY 2011. However, we are addressing this issue in this FY 2012 proposed rule.

Deep brain stimulation is a surgical treatment that involves the implantation of a neurostimulator, used in the treatment of essential tremor, Parkinson's disease, dystonia, and chronic pain. The commenter recommended that CMS assign the combination of procedure codes representing rechargeable systems for deep brain stimulation therapy, procedure code 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)) and procedure code 86.98 (Insertion or replacement of dual array rechargeable neurostimulator pulse generator) to MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemo Implant) and MS–DRG 024 (Craniotomy with Major Device Implant/Acute Complex CNS PDX without MCC).

The commenter stated that this recommendation would allow all full system dual array deep brain stimulation cases to be appropriately grouped to the same MS–DRGs. Currently, procedure codes 02.93 and 86.98 are assigned to MS–DRG 025 (Craniotomy and Endovascular Intracranial Procedures with MCC), MS–DRG 026 (Craniotomy and Endovascular Intracranial Procedures with CC), and MS–DRG 027 (Craniotomy and Endovascular Intracranial Procedures without CC/MCC), while the procedure codes for the nonrechargeable dual array systems, procedure codes 02.93 and 86.95 (Insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable), are already assigned to MS–DRGs 023 and 024. The commenter stated that the procedures to implant the rechargeable and nonrechargeable dual array systems are similar clinically as well as comparable in resource utilization.

We analyzed FY 2010 MedPAR data and found a total of 16 full system rechargeable dual array deep brain stimulation systems reported with procedure codes 02.93 and 86.98 assigned to MS–DRGs 025 through 027. We found one case assigned to MS–DRG 025 and one case assigned to MS–DRG 026. The majority of the cases, 14, were assigned to MS–DRG 027, with average costs of approximately $23,870 and an average length of stay of approximately 2.2 days. We found that the deep brain stimulation cases assigned to MS–DRG 027 had higher average costs than the overall cases assigned to MS–DRG 027 of approximately $14,200. However, the average length of stay was shorter for these cases than the overall length of stay for MS–DRG 027 cases of approximately 3.7 days.

We also examined the data for the nonrechargeable dual array systems to assess the commenter's assumption that both the rechargeable and nonrechargeable dual array systems are similar in resource use. We found 155 total nonrechargeable dual array systems (procedure codes 02.93 and 86.95) assigned to MS–DRGs 023 and 024. There were 5 cases assigned to MS–DRG 023, with average costs of approximately $36,159 and an average length of stay of approximately 10 days. We found that the majority of the cases, 150, were assigned to MS–DRG 024, with average costs of approximately $25,855 and an average length of stay of approximately 2.2 days. We believe that these data support the commenter's statement that, for the majority of these cases, the resource use is similar for both systems.

For comparison purposes, if we propose the changes that the commenter suggested, those deep brain stimulation cases currently assigned to MS–DRG 027 and the one case assigned to MS–DRG 026 (with average costs of approximately $27,836) would be reassigned to MS–DRG 024. The average costs of approximately $23,870 of these deep brain stimulation cases assigned to MS–DRG 027 are similar to the overall average costs of approximately $23,249 for MS–DRG 024. The one case assigned to MS–DRG 025 (with average costs of approximately $29,361) would be reassigned to MS–DRG 023 (with average costs of approximately $34,168). The following table illustrates our findings:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 023 - All cases	4,238	11.8	$34,168
MS-DRG 023 - Cases with codes 02.93 and 86.95	5	10.0	$36,159
MS-DRG 024 - All cases	1,592	7.6	$23, 249
MS-DRG 024 - Cases with codes 02.93 and 86.95	150	2.2	$25,855
MS-DRG 025 - All cases	11,505	11.0	$29,524
MS-DRG 025 - Cases with codes 02.93 and 86.98	1	2.0	$29, 361
MS-DRG 026 - All cases	9,782	7.0	$19,125
MS-DRG 026 - Cases with codes 02.93 and 86.98	1	3.0	$27,836
MS-DRG 027 - All cases	10,936	3.7	$14,200
MS-DRG 027 - Cases with codes 02.93 and 86.98	14	2.2	$23,870

Based on our findings, we believe that the data support reassigning the combination of procedure codes representing rechargeable systems for deep brain stimulation therapy, code 02.93 and code 86.98, to MS–DRGs 023 and 024. Our clinical advisors support this reassignment. Therefore, we are proposing to assign rechargeable dual array systems for deep brain stimulation cases identified by reporting both procedure codes 02.93 and 86.98 to MS–DRGs 023 and 024 for FY 2012. We invite public comment on our proposal to assign these cases to MS–DRG 023 and 024 for FY 2012.

3. MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth, and Throat): Skull Based Surgeries

We received a request from a commenter recommending that CMS reclassify skull-based surgical procedures that are currently assigned to MS–DRGs 135 and 136 (Sinus and Mastoid Procedures with CC/MCC and without CC/MCC, respectively) and reassign them to MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively). The commenter stated that the current MS–DRG assignment does not reflect the resource utilization and technical complexity of these difficult procedures when performed for anterior skull base tumors.

Skull (or cranial) based surgery is performed for a variety of serious medical conditions including esthesioneuroblastomas, which are rare, malignant tumors that arise from the epithelium overlying the olfactory bulb; sinonasal melanomas, which are malignant melanomas that may develop in the mucosa of the nose and sinuses; and sinonasal undifferentiated carcinomas, which are rapidly growing malignant tumors arising in the nasal cavity and/or sinuses. These types of conditions are generally identified by the following ICD–9–CM diagnosis codes:

- 160.0 (Malignant neoplasm of nasal cavities)
- 160.1 (Malignant neoplasm of auditory tube, middle ear, and mastoid air cells)
- 160.2 (Malignant neoplasm of maxillary sinus)
- 160.3 (Malignant neoplasm of ethmoidal sinus)
- 160.4 (Malignant neoplasm of frontal sinus)
- 160.5 (Malignant neoplasm of sphenoidal sinus)
- 160.8 (Malignant neoplasm of other accessory sinuses)
- 160.9 (Malignant neoplasm of accessory sinus, unspecified)
- 210.7 (Benign neoplasm of nasopharynx)
- 212.0 (Benign neoplasm of nasal cavities, middle ear, and accessory sinuses)

According to the commenter, procedure code 22.63 (Ethmoidectomy) describes the type of surgery being performed for these patients and is currently assigned to MS–DRGs 135 and 136.

Using the FY 2010 MedPAR file, we examined data on cases identified by procedure code 22.63 when reported with one of the above listed diagnosis codes in MS–DRGs 135 and 136. We found a total of 402 cases in MS–DRG 135 with an average length of stay of 6.30 days and average costs of $12,869. We found only 23 cases in MS–DRG 135 identified by procedure code 22.63 with one of the diagnosis codes listed above with an average length of stay of 3.96 days and average costs of $10,510. In MS–DRG 136, there were a total of 320 cases with an average length of stay of 2.36 days and average costs of $6,683. We found only 27 cases in MS–DRG 136 identified by procedure code 22.63 with one of the diagnosis codes listed above with an average length of stay of 2.04 days and average costs of $6,844. As shown in the table below, the cases reporting procedure code 22.63 in MS–DRGs 135 and 136 have a lower volume, a shorter length of stay, and primarily lower average costs compared to all cases in MS–DRGs 135 and 136. The data demonstrate that these cases are appropriately assigned to their current MS–DRG classifications.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 135 - All cases	402	6.30	$12,869
MS-DRG 135 -Cases with procedure code 22.63 and diagnosis code 160.0 through 160.9 or 210.7 or 212.0	23	3.96	$10,510
MS-DRG 136 -All cases	320	2.36	$6,683
MS-DRG 136 - Cases with procedure code 22.63 and diagnosis code 160.0 through 160.9 or 210.7 or 212.0	27	2.04	$6,844

We also analyzed claims data for MS–DRGs 25 through 27. We determined that if the cases identified by procedure code 22.63 were to be reassigned to MS–DRGs 25–27, they would be significantly overpaid. As shown in the table below, we found that the average costs for these MS–DRGs range from $14,200 to $29,524.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 025 - All cases	11,505	10.95	$29,524
MS-DRG 026 - All cases	9,782	7.00	$19,125
MS-DRG 027 - All cases	10,936	3.71	$14,200

In summary, the data do not support moving cases with procedure code 22.63 when reported with one of the previously listed diagnosis codes from MS–DRGs 135 and 136 to MS–DRGs 25, 26 and 27. We invite public comment on our proposal not to make any MS–DRG modifications for these codes for FY 2012.

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

a. Percutaneous Mitral Valve Repair With Implant

Procedure code 35.97 (Percutaneous mitral valve repair with implant) was created for use beginning October 1, 2010 (FY 2011) after the concept of a percutaneous valve repair was presented and approved at the February 2010 ICD–9–CM Coordination and Maintenance Committee Meeting. Procedure code 35.97 was created at that time to describe the MitraClip™ device and any other percutaneous mitral valve repair devices currently on the market. This procedure code is assigned to the following MS–DRGs: 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively); 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents); 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC); 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents); 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC); 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI with MCC); and 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI without MCC).

According to the Food and Drug Administration's (FDA's) terms of the clinical trial for MitraClip™, the device is to be implanted in patients without any additional surgeries performed. Therefore, based on these terms, we believe that the most likely MS–DRG assignments would be MS–DRGs 250 and 251, as described above. However, because procedure code 35.97 has only been in use since October 1, 2010, there are no claims data in the most recent MedPAR update file with which to evaluate any alternative MS–DRG assignments. Therefore, we are not proposing to make any MS–DRG changes for procedure code 35.97 for FY 2012. We are proposing to keep procedure code 35.97 in its current MS–DRG assignments. We invite public comment on this proposal.

b. Aneurysm Repair Procedure Codes

Thoracic aorta defects, such as aneurysm, dissection, or injury, are uncommon but serious conditions that may arise from a disease or an accident. Some patients can be medically managed but most patients are treated with surgery. Often these defects result in death if they are not diagnosed and treated promptly. Currently, there are two techniques used for repair of aortic defects; both are O.R. procedures performed in an inpatient hospital setting. These two procedures are described by ICD–9–CM procedure codes 38.45 (Resection of vessel with replacement, thoracic vessel) and 39.73 (Endovascular implantation of graft in thoracic aorta). Both procedure codes 38.45 and 39.73 are currently assigned to MS–DRGs 237 (Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm Repair) and 238 (Major Cardiovascular Procedures without MCC).

We received a request that we consider the reassignment of procedure codes 38.45 and 39.73 within the MS–DRG structure by removing the procedure codes from MS–DRGs 237 and 238 and adding them to a more clinically coherent set of MS–DRGs reflecting higher resource consumption. The requestors believed that, based on their analysis of MedPAR claims data of

MS–DRGs 237 and 238, the resource utilization of both the endovascular and open repairs of the abdominal and thoracic aortas are higher than the overall average resource utilization for the MS–DRGs to which these procedures are currently assigned. The requestors also believed that an unusually high number of cases probably fall into cost outlier status.

We reviewed the MedPAR claims data for these two procedure codes. Our findings are shown in the following two tables.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 237 - All cases	20,680	10.03	$34,268
MS-DRG 237 - Cases with procedure code 39.73	1,851	7.73	$41,033
MS-DRG 237 - Cases without procedure code 39.73	18,829	10.26	$33,603
MS-DRG 238 - All cases	35,705	4.08	$20,597
MS-DRG 238 - Cases with procedure code 39.73	0	0	0
MS-DRG 238 - Cases without procedure code 39.73	35,705	4.08	$20,597

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 237 - All cases	20,680	10.03	$34,268
MS-DRG 237 - Cases with procedure code 38.45	448	13.29	$51,953
MS-DRG 237 - Cases without procedure code 38.45	20,234	9.96	$33,878
MS-DRG 238 - All cases	35,705	4.08	$20,597
MS-DRG 238 - Cases with procedure code 38.45	466	7.29	$30,219
MS-DRG 238 - Cases without procedure code 38.45	35,239	4.03	$20,465

Our findings of the analysis of the cases with procedure code 39.73 showed that the average costs are substantially higher than those costs for the cases overall in both MS–DRGs 237 and 238. We found that the average length of stay for the 1,851 cases identified in MS–DRG 237 is somewhat lower at 7.73 days than the average length of stay of 10.26 days in cases not containing procedure code 39.73.

Our findings of the analysis of the cases with procedure code 38.45 showed that both the average costs and the average length of stay are considerably higher than the average costs and the average length of stay for those cases without procedure code 38.45.

In addition, we reviewed the cases in which both procedure codes 38.45 and 39.73 were documented during the same admission. As can be seen in the charts below, we found 22 cases in which both procedure codes 38.45 and 39.73 were reported. Therefore, the sum of the values in the next two charts below will differ from the charts above because of the cases containing both procedure codes that have been removed and the data have been reworked.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 237 - All cases	20,680	10.03	$34,268
MS-DRG 237 - Cases with procedure code 39.73 and without procedure code 38.45	1,829	7.68	$40,862
MS-DRG 237 - Cases with procedure code 38.45 and without procedure code 39.73	424	13.36	$51,783
MS-DRG 238 - All cases	35,705	4.08	$20,597
MS-DRG 238 - Cases with procedure code 39.73 and without procedure code 38.45	0	0	0
MS-DRG 238 - Cases with procedure code 38.45 and without procedure code 39.73	466	7.29	$30,219

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 237 - All cases	20,680	10.03	$34,268
MS-DRG 237 - Cases with procedure code 38.45 and with procedure code 39.73	22	11.86	$55,243
MS-DRG 237 - Cases without procedure code 38.45 or procedure code 39.73	18,405	10.19	$33,184
MS-DRG 238 - All cases	35,705	4.08	$20,597
MS-DRG 238 - Cases with procedure code 38.45 and with procedure code 39.73	0	0	0
MS-DRG 238 - Cases without procedure code 38.45 or procedure code 39.73	35,239	4.03	$20,465

We found in our analysis of the claims data for cases with both procedure codes 38.45 and 39.73 that the average costs are substantially higher than those costs for the cases overall in MS–DRG 237. In addition, we found that the average length of stay for the 22 cases with both procedure codes 38.45 and 39.73 is higher at 11.86 days than the average length of stay of 10.03 days for all cases in MS–DRG 237.

Our analysis of the claims data for the procedure codes in MDC 5 showed that procedure code 34.85 is also assigned to MS–DRGs 228 (Other Cardiothoracic Procedures with MCC), 229 (Other Cardiothoracic Procedures with CC), and 230 (Other Cardiothoracic Procedures without CC/MCC) when it occurs in combination with procedure code 38.44 (Resection of vessel with replacement, aorta, abdominal). We found that when procedure code 39.73 is not assigned to MS–DRGs 228 through 230, there are no cases reported.

The table below shows our findings of the average costs and the average length of stay for procedure code 38.45 in combination with procedure code 38.44 in MS–DRGs 228 through 230 and the average costs and the average length of stay in all cases in MS–DRGs 228 through 230 when both procedure codes 38.45 and 38.44 are not assigned.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 228 - All cases	2,084	13.79	$49,488
MS-DRG 228 - Cases with procedure code 38.45 and procedure code 38.44	276	15.18	$56,246
MS-DRG 228 - Cases without procedure code 38.45 and without procedure code 38.44	1,808	13.58	$48,456
MS-DRG 229 - All cases	2,354	8.31	$31,148
MS-DRG 229 - Cases with procedure code 38.45 and procedure code 38.44	157	10.68	$37,723
MS-DRG 229 - Cases without procedure code 38.45 and without procedure code 38.44	2,197	8.14	$30,678
MS-DRG 230 - All cases	628	5.45	$24,236
MS-DRG-230 - Cases with procedure code 38.45 and procedure code 38.44	34	7.18	$27,054
MS-DRG 230 - Cases without procedure code 38.45 and without procedure code 38.44	594	5.35	$24,075

Our findings show that both the average length of stay and average costs are higher in those cases containing procedure code 34.85 than those cases without this procedure code in MS–DRGs 228 through 230.

We then analyzed the 1,851 cases containing procedure code 39.73 in MS–DRGs 237 and 238 and the 912 cases containing procedure code 38.45 in MS–DRGs 237 and 238 to determine if they would meet the established criteria for a 3-way severity of illness split. This criterion is described in section III.G.1.c. of this preamble. The chart below shows our findings, with MS–DRG 237 acting as a severity of illness proxy for all cases, as there were no cases in MS–DRG 238. In the chart, the extensions "–1," "–2," and "–3" correspond to severity levels, with "–1" representing cases with MCC, "–2" representing cases with CC, and "–3" representing cases without CC/MCC.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 237-1 - All cases	20,680	10.03	$34,268
MS-DRG 237-1 - Cases with procedure code 39.73	637	12.14	$57,834
MS-DRG 237-1 - Cases with procedure code 38.45	446	13.29	$51,954
MS-DRG 237-2 - All cases	17,356	5.73	$22,083
MS-DRG 237-2 - Cases with procedure code 39.73	659	6.89	$38,673
MS-DRG 237-2 - Cases with procedure code 38.45	353	8.14	$31,480
MS-DRG 237-3 - All cases	18,349	2.52	$19,183
MS-DRG 237-3 - Cases with procedure code 39.73	555	3.65	$27,993
MS-DRG 237-3 - Cases with procedure code 38.45	113	6.30	$26,280

Our next step was to analyze the claims data for the cases in the clinically coherent MS–DRGs to which we are proposing to move these cases. These six MS–DRGs are: 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC); 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC); 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC); 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC), 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC); and 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC). For the sake of the grouping algorithm, procedure codes 39.73 and 38.45 must also be added to MS–DRGs 216 through 219. However, if these codes are documented in cases in which a cardiac catheterization occurs, they will be "trumped" by those catheterizations. Therefore, when we reviewed the data in order to make length of stay and cost comparisons, we only used the three MS–DRGs to which procedure codes 39.73 and 38.45 would appear without cardiac catheterization; that is MS–DRGs 219, 220, and 221. Our findings describing these three MS–DRGs are displayed in the following chart:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 219	12,805	12.76	$51,399
MS-DRG 220	15,988	7.65	$34,270
MS-DRG 221	4,043	5.90	$28,974

Our evaluation of the severity levels in the cases containing procedure codes 39.73 and 38.45 using the proxy MS–DRGs 237–1, 237–2, and 237–3 compared to the claims data in the table above with MS–DRGs 219 through 221 demonstrates that the cases are similar in resource consumption. In addition, the cases are clinically coherent.

By proposing to move procedure code 38.45 to MS–DRGs 216 through 221, we do not believe that there is a need for combination codes 38.45 plus 38.44 to be specifically assigned to MS–DRGs 228, 229, and 230. Because MS–DRGs 216 through 221 are higher in the surgical hierarchy for MDC 5 than MS–DRGs 228 through 230, the result of the proposal would be that either procedure code 38.45 by itself or in combination with procedure code 38.44 will always be assigned to MS–DRGs 216 through 221. When reported alone, under our proposal, procedure code 38.44 would continue to be assigned to MS–DRGs 237 and 238, as it has been in the past.

Therefore, for FY 2012, we are proposing to move procedure codes 38.45 and 39.73 from MS–DRGs 237 and 238 and to add these codes to MS–DRGs 216, 217, 218, 219, 220, and 221 based on our findings of similar resource consumption and clinical coherence. To conform to this proposed change, we also are proposing to change the title of MS–DRG 237 (Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm Repair) by removing the terms "or Thoracic Aortic Aneurysm Repair." Therefore, the new proposed title of MS–DRG 237 would be "Major Cardiovascular Procedures with MCC." We invite public comment on these proposals.

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

a. Artificial Discs

In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received a public comment that was outside of the scope of any proposal in that proposed rule. The commenter urged CMS to reassign procedure code 84.62 (Insertion of total spinal disc prosthesis, cervical) from MS–DRG 490 (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator) into MS–DRGs 471 through 473 (Cervical Spinal Fusion with MCC, with CC, and without CC/MCC, respectively). In addition, the commenter requested that CMS reassign procedure code 84.65 (Insertion of total spinal disc prosthesis, lumbosacral) from MS–DRG 490 (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator) to MS–DRGs 459 and 460 (Spinal Fusion Except Cervical with MCC and without MCC, respectively). However, the commenter also provided an alternative option to reassigning the procedure codes to different MS–DRGs. The commenter suggested the creation of a new, separate MS–DRG for the two artificial disc procedures if reassignment to the fusion MS–DRGs was not feasible.

We refer the reader to the FY 2008 IPPS proposed rule and final rule with comment period (72 FR 24731 through 24735 and 47226 through 47232) for discussion on the comprehensive evaluation of all the spinal DRGs in the development of the MS–DRG classification system. The modifications made to the spinal DRGs for FY 2008 recognized the similar utilization of resources, differences in levels of severity, and the complexity of the services being performed on patients undergoing the various types of spinal procedures.

We analyzed FY 2010 MedPAR claims data for procedure codes 84.62 and 84.65 in MS–DRG 490 and compared those results to the claims data for MS–DRGs 459, 460, 471, 472, and 473. We found a total of 19,840 cases in MS–DRG 490 with an average length of stay of 4.24 days and average costs of $11,940. As displayed in the chart below, we found 97 cases reporting procedure code 84.62, with an average length of stay of 1.80 days and average costs of $13,194 in MS–DRG 490. We also found 35 cases reporting procedure code 84.65, with an average length of stay of 2.91 days and average costs of $20,753. While average costs for the artificial disc cases were slightly higher ($1,254 for procedure code 84.62 and $8,813 for procedure code 84.65) compared to the average cost for all cases in MS–DRG 490, the artificial disc cases were of extremely low volume and reflected shorter lengths of stay compared to all the cases in MS–DRG 490.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 459 – All cases	3,650	8.92	$40,218
MS-DRG 460 – All cases	60,865	3.75	$25,268
MS-DRG 471– All cases	2,686	8.92	$29,837
MS-DRG 472– All cases	8,586	3.78	$18,494
MS-DRG 473– All cases	24,323	1.80	$13,775
MS-DRG 490 – All cases	19,840	4.24	$11,940
MS-DRG 490 – Cases with code 84.62	97	1.80	$13,194
MS-DRG 490 – Cases with code 84.65	35	2.91	$20,753

We recognize the disparity in average costs for cases reporting the insertion of a cervical or lumbar artificial disc in MS–DRG 490 compared to all the cases in that MS–DRG. However, we do not believe this supports reassignment of procedure codes 84.62 and 84.65 to the MS–DRGs for spinal fusion as the commenter requested. Even with the disparity in costs, clinically, the insertion of an artificial disc is not a spinal fusion. Therefore, reassignment of the artificial disc cases to the fusion MS–DRGs would be clinically inappropriate. In addition, for certain Medicare populations, the insertion of an artificial disc is considered a noncovered procedure.

As stated earlier, the commenter also provided an alternative option to reassigning procedure codes 84.62 and 84.65. The commenter suggested the creation of a new, separate MS–DRG for the two artificial disc procedures if reassignment to the fusion MS–DRGs was not feasible. In our evaluation of the claims data and as shown above in the data chart, the artificial disc cases are of extremely low volume; therefore, we do not believe the findings warrant the creation of a separate MS–DRG.

We invite public comment on our proposal not to reassign procedure code 84.62 from MS–DRG 490 to MS–DRGs 471 through 473 and procedure code 84.65 from MS–DRG 490 to MS–DRGs 459 and 460. We also invite public comment on our proposal not to create a new, separate MS–DRG for artificial disc procedures (codes 84.62 and 84.65) for FY 2012.

b. Major Joint Replacement or Reattachment of Lower Extremities

We received a request to add an additional severity level for MS–DRG 469 (Major Joint Replacement or Reattachment of Lower Extremity with MCC) and MS–DRG 470 Major Joint Replacement or Reattachment of Lower Extremity without MCC). We examined FY 2010 MedPAR claims data to determine if we could subdivide the base MS–DRG into three severity levels: With MCC, with CC, and without CC/MCC. We applied the criteria used in the development of the MS–DRGs included in the FY 2008 IPPS final rule with comment period (72 FR 47169). We refer readers to this final rule with comment period for a complete description of these criteria. As discussed earlier, the original criteria were based on average charges. However, subsequent to the FY 2007 IPPS final rule (71 FR 47882), we now use average costs. The five criteria using costs are listed below. In order to warrant creation of a CC or an MCC subgroup within a base MS–DRG, the subgroup must meet all of the following five criteria:

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

The following table shows our determination of the number of cases and average costs by MCC, CC, and non-CC levels.

MS-DRGs 469 and 470	Number of Cases	Average Length of Stay	Average Costs
Cases with MCC	25,717	7.72	$21,016
Cases with CC	179,116	3.99	$14,233
Cases without CC/MCC	220,739	3.21	$13,250
Total	425,572	3.8	$14,133

We determined that these cases do not meet our five criteria for adding a new severity level. The cases failed to meet criterion four (requiring at least a 20-percent difference in average costs between subgroups) and criterion five (requiring a $2,000 difference in average costs between subgroups). Therefore, we are not proposing the addition of a new severity level for the base MS–DRG. Instead, we are proposing to maintain the two existing severity levels for MS–DRGs 469 and 470. We welcome public comments on our proposal not to add an additional severity level to MS–DRGs 469 and 470.

c. Combined Anterior/Posterior Spinal Fusion

A manufacturer requested that CMS reassign spinal fusion cases utilizing the AxiaLIF technology from MS–DRGs 459 and 460 (Spinal Fusion Except Cervical with MCC and without MCC, respectively) to MS–DRGs 453, 454, and

455 (Combined Anterior/Posterior Spinal Fusion with MCC, with CC, and without CC/MCC, respectively). The commenter stated that an anterior lumbar interbody spinal fusion performed with a lateral approach, the extreme lateral interbody fusion (XLIF®), with posterior spinal fixation, can report two codes resulting in assignment to the combined fusion MS–DRGs. The commenter also stated that the AxiaLIF technology, which is also utilized in an anterior lumbar interbody spinal fusion and uses a pre-sacral approach, can only report one code, resulting in assignment to the single fusion MS–DRGs. The commenter expressed concern that the payment incentives are not properly aligned for the recently available minimally invasive spinal fusion technologies. The commenter compared the XLIF® to the AxiaLIF and urged CMS to consider the AxiaLIF technology similar to the XLIF® for purposes of MS–DRG assignment.

Spinal fusion is a surgical procedure that joins two or more vertebrae by the use of bone graft (or bone graft substitute), with the goal of maintaining alignment, providing stability, decreasing pain, and restoring the function of the spinal nerves. Routinely, a spinal fusion also utilizes internal fixation devices (instrumentation) to assist in stabilizing the spine. These fixation devices may include pedicle screws, cages, rods, or plates. Effective October 1, 2010, ICD–9–CM procedure code 81.06 (Lumbar and lumbosacral fusion of the anterior column, anterior technique) describes the XLIF® procedure, and code 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique) describes the AxiaLIF technology.

The spinal fusion codes and their corresponding MS–DRG assignment include the use of bone graft and internal fixation. The requestor's comment regarding the assignment of one procedure code for one technology versus assigning two procedure codes for another technology indicates that the commenter may not fully understand the MS–DRG GROUPER logic for spinal fusions. For example, if an anterior lumbar interbody fusion is performed and posterior spinal fixation (or instrumentation) is also utilized, this requires one code and results in a single fusion MS–DRG assignment. However, if a posterior spinal fusion (procedure code 81.07 (Lumbar and lumbosacral fusion of the posterior column, posterior technique) was performed in addition to an anterior fusion, for example, the XLIF® procedure (procedure code 81.06), that scenario would necessitate the assignment of both codes, resulting in assignment to the combined spinal fusion MS–DRGs (453, 454, or 455). MS–DRGs 453, 454, and 455 were created to capture patients who have both an anterior and posterior fusion. We believe the requestor may have confused the terms "fixation" and "fusion" for MS–DRG assignment in its request.

We analyzed the FY 2010 MedPAR data to evaluate claims reporting procedure codes 81.06, 81.07, and 81.08 in MS–DRGs 456 through 458 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or 9+ Fusions with MCC, with CC and without CC/MCC, respectively) and MS–DRGs 459 and 460. We found a total of 1,115 cases in MS–DRG 456, with an average length of stay of 13.14 days and average costs of $63,856. We found 278 cases reporting procedure code 81.08, with an average length of stay of 12.04 days and average costs of $56,585. Similar results can be seen for procedure code 81.08 in the remaining MS–DRGs as shown in the chart below in terms of volume, length of stay, and average cost. Clearly, the data demonstrate that the AxiaLIF technology (procedure code 81.08) is appropriately assigned to its current MS–DRG assignments, as is the XLIF® procedure (procedure code 81.06).

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 456 – All cases	1,115	13.14	$63,856
MS-DRG 456 – Cases with code 81.06	54	14.37	$52,392
MS-DRG 456 – Cases with code 81.07	22	12.32	$46,828
MS-DRG 456 – Cases with code 81.08	278	12.04	$56,585
MS-DRG 457 – All cases	3,079	6.74	$41,500
MS-DRG 457 – Cases with code 81.06	119	6.42	$36,468
MS-DRG 457 – Cases with code 81.07	98	6.49	$36,532
MS-DRG 457 – Cases with code 81.08	1,194	5.73	$35,272
MS-DRG 458 – All cases	1,389	3.91	$32,946
MS-DRG 458 – Cases with code 81.06	115	3.49	$29,089
MS-DRG 458 – Cases with code 81.07	76	3.16	$30,551
MS-DRG 458 – Cases with code 81.08	827	3.60	$30,570
MS-DRG 459 – All cases	3,650	8.92	$40,218
MS-DRG 459 – Cases with code 81.06	164	9.12	$40,150
MS-DRG 459 – Cases with code 81.07	165	8.65	$37,970
MS-DRG 459 – Cases with code 81.08	2,468	8.25	$38,010
MS-DRG 460 – All cases	60,865	3.75	$25,268
MS-DRG 460 – Cases with code 81.06	2,681	3.27	$26,464
MS-DRG 460 – Cases with code 81.07	3,709	3.67	$23,334
MS-DRG 460 – Cases with code 81.08	46,565	3.66	$24,571

We also analyzed data for combinations of the spinal fusion codes that result in assignment to MS–DRGs 453, 454, and 455. We evaluated the following combinations:

- 81.06 (Lumbar and lumbosacral fusion of the anterior column, anterior technique) and 81.07 (Lumbar and lumbosacral fusion of the posterior column, posterior technique).
- 81.06 (Lumbar and lumbosacral fusion of the anterior column, anterior technique) and 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique).

We further analyzed data with the following combination of spinal fusion codes in MS–DRGs 456, 457, and 458 and MS–DRGs 459 and 460:

- 81.07 (Lumbar and lumbosacral fusion of the posterior column, posterior technique) and 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique).

The chart below shows the results of the data analysis for the combination of procedure codes listed above where an anterior and posterior spinal fusion was performed in the same episode of care. There were a total of 1,190 cases in MS–DRG 453, with an average length of stay of 13.08 days and average costs of $71,693. The cases reporting the combination of procedure codes 81.06 and 81.08 in this same MS–DRG totaled 431, with an average length of stay of 11.59 days and average costs of $69,859. Results for the procedure code combination (81.06 and 81.08) in MS–DRGs 454 and 455 with regard to volume of cases, length of stay, and average costs data also support that these spinal fusion procedure code combinations are appropriately placed in their current MS–DRG assignments. Likewise, for MS–DRGs 456, 457, and 458, the data support that the spinal fusion procedure code combinations of 81.07 and 81.08 are appropriately placed in their current MS–DRG assignments. There were a total of 1,115 cases in MS–DRG 456 with an average length of stay of 13.14 days and average costs of $68,856. The cases reporting the combination of procedure codes 81.07 and 81.08 in this same MS–DRG totaled 54, with an average length of stay of 14.37 days and average costs of $52,392. Results for the procedure code combination (81.07 and 81.08) in MS–DRGs 457 and 458 with regard to volume of cases and average length of stay were lower compared to all the cases in those two MS–DRGs. While the data show higher average costs for the procedure code combination of 81.07 and 81.08 in MS–DRGs 457 and 458, as stated previously, the volume was extremely low.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 453 – All cases	1,190	13.08	$71,693
MS-DRG 453 – Cases with codes 81.06 and 81.07	8	14.00	$109,089
MS-DRG 453 – Cases with codes 81.06 and 81.08	431	11.59	$69,859
MS-DRG 454 – All cases	3,052	6.38	$48,311
MS-DRG 454 – Cases with codes 81.06 and 81.07	47	6.83	$60,743
MS-DRG 454 – Cases with codes 81.06 and 81.08	1,825	5.71	$47,144
MS-DRG 455 – All cases	2,747	3.63	$37,378
MS-DRG 455 – Cases with codes 81.06 and 81.07	40	4.28	$47,794
MS-DRG 455 – Cases with codes 81.06 and 81.08	2,053	3.43	$37,793
MS-DRG 456 – All cases	1,115	13.14	$63,856
MS-DRG 456 – Cases with codes 81.07 and 81.08	54	14.37	$52,392
MS-DRG 457 – All cases	3,079	6.74	$41,500
MS-DRG 457 – Cases with codes 81.07 and 81.08	29	5.97	$60,820
MS-DRG 458 – All cases	1,389	3.91	$32,946
MS-DRG 458 – Cases with code 81.07 and 81.08	23	3.22	$51,942

As the focus of the analysis was to evaluate procedure code 81.08 in comparison to procedure code 81.06, we believe the AxiaLIF technology (procedure code 81.08) is grouped appropriately in its current MS–DRG assignments, as is the XLIF® procedure (procedure code 81.06). The volume, length of stay, and cost data analyzed demonstrate that the complexity of services and resources utilized for each of these technologies are properly accounted for in their respective MS–DRG assignments. Therefore, the data does not support making changes for procedure code 81.08. As a result, we are not proposing to reassign cases reporting this procedure code to the combined fusion MS–DRGs. We invite public comment on our proposal to not reassign procedure code 81.08 from MS–DRGs 456 through 460 to MS–DRGs 453 through 455 for FY 2012.

6. MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue, and Breast): Excisional Debridement of Wound, Infection, or Burn

We received a request that we remove procedure code 86.22 (Excisional debridement of wound, infection, or burn) from the list of codes considered to be O.R. procedures. The commenter stated that many inpatient excisional debridements are performed in a patient's room instead of in an operating room. The commenter believed that the original assignment of procedure code 86.22 to the O.R. list served to help reflect the resource intensity required by a patient with wounds and ulcers that required an excisional debridement. The commenter stated that, by doing so, the code served as a proxy for severity of illness in the original CMS DRGs prior to the implementation of MS–DRGs in FY 2008. The commenter stated that the creation of the most serious pressure ulcer codes for stage 3 and stage 4 pressure ulcers (codes 707.23 and 707.24) allows these conditions to be classified as MCCs. Therefore, the commenter stated that the need to use procedure code 86.22 to capture severity of illness was no longer needed. The commenter also stated that procedure code 86.22 is a non-O.R. code under the APR–DRGs and does not affect the DRG assignment. The commenter requested that procedure code 86.22 be changed from an O.R. procedure code to a non-O.R. procedure code.

As the commenter stated, excisional debridements are currently captured in procedure code 86.22. Procedure code 88.22 is classified as an O.R. procedure in the current MS–DRGs and, therefore, leads to a surgical MS–DRG assignment. We examined MedPAR claims data on all excisional debridement cases and found that these debridement cases use appreciably fewer resources than other cases in their current surgical DRGs. However, we determined that if we were to classify debridement cases as non-O.R. cases and assign them to medical DRGs, we would significantly underpay these cases. The following chart shows differences in average costs for all excisional debridement cases compared to other cases within their current MS–DRG and compared to medical DRGs to which the patients would be assigned if the procedure were reclassified as a non-O.R. procedure.

Procedure Code	All Cases with No Other OR Procedure	Average Cost (A)	Average Costs in Surgical DRGs to Which the Patients Are Assigned (B)	Average Costs in Medical DRGs to Which the Patients Would Be Assigned (C)
86.22	32,152	$12,427	$17,332	$8,070

The chart illustrates that when debridement is the only O.R. procedure, it is assigned to MS–DRGs that have an average cost that is approximately $5,000 more than the actual cost of the debridement ($12,427 versus $17,332). Conversely, if the debridement is made a non-O.R. code, it would, on average, be assigned to MS–DRGs that have an average cost that is approximately $4,000 less than the actual cost of the debridement ($8,070 versus $12,427). Therefore, we believe it would be inappropriate to propose to classify these procedures as a non-O.R. procedure.

We explored alternative approaches to classifying procedure code 86.22 as a non-O.R. procedure. We evaluated the possibility of removing excisional debridements from their current MS–DRG assignments within the following skin-related MS–DRGs, where they are combined with skin grafts, and creating a new set of debridement MS–DRGs. The current MS–DRGs that combine skin grafts and debridements into the same MS–DRGs are as follows:

- MS–DRGs 573 through 575 (Skin Graft &/or Debridement for Skin Ulcer or Cellulitis with MCC, with CC, and without CC/MCC, respectively).
- MS–DRGs 576 through 578 (Skin Graft &/or Debridement Except for Skin Ulcer or Cellulitis with MCC, with CC, and without CC/MCC, respectively).

We analyzed MedPAR claims data on the severity level of graft cases without any debridements in these six MS–DRGs. Our findings are shown in the chart below.

SKIN GRAFTS WITHOUT DEBRIDEMENTS

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRGs 573-575 - Cases with severity level of MCC	751	14.56	$23,975
MS-DRGs 573-575 - Cases with severity level of CC	1,720	10.16	$14.869
MS-DRGs 573-575 - Cases with severity level of without CC/MCC	540	5.36	$8,469
MS-DRGs 576-578 - Cases with severity level of MCC	335	10.28	$22,996
MS-DRGs 576-578 - Cases with severity level of CC	1,482	5.28	$11,299
MS-DRGs 576-578 - Cases with severity level of without CC/MCC	1,849	3.01	$6,986

We compared these data to a proposed new set of skin-related MS–DRGs that would include only debridements. The results of the findings of the severity levels of debridements without skin grafts in these six MS–DRGs are shown in the chart below.

DEBRIDEMENTS WITHOUT SKIN GRAFTS

MS-DRG	Number of Cases	Average Length of Stay	Average costs
MS-DRG 573-575 - Cases with severity level of MCC	3,177	11.73	$18,381
MS-DRG 573-575 - Cases with severity level of CC	6,649	7.67	$10,730
MS-DRG 573-575 - Cases with severity level of without CC/MCC	2,555	4.94	$6,372
MS-DRG 576-578 - Cases with severity level of MCC	271	11.59	$19,429
MS-DRG 576-578 - Cases with severity level of CC	638	7.61	$11,913
MS-DRG 576-578 - Cases with severity level of without CC/MCC	285	4.45	$6,928

Our findings indicate that the graft procedure cases have higher average costs than the excisional debridement cases. The average costs for the excisional debridement cases in MS–DRGs 573 through 575 compared to the debridement cases in MS–DRGs 576 through 578 are very similar. We believe that the data support creating a single set of skin-related excisional debridement MS–DRGs composed of cases previously captured in MS–DRGs 573 through 575 as well as MS–DRGs 576 through 578. The following chart illustrates those combined average costs.

EXCISIONAL DEBRIDEMENTS FROM MS-DRGs 573 THROUGH 578 SPLIT ON SEVERITY LEVEL

MS-DRGs 573 – 578	Number of Cases	Average Length of Stay	Average Costs
Combined Excisional Debridement Cases with Severity Level of MCC	3,448	11.71	$18,463
Combined Excisional Debridement Cases with Severity Level of CC	7,287	7.76	$10,833
Combined Excisional Debridement Cases with Severity Level of without CC/MCC	2,840	4.89	$6,428

We believe that the data support separating skin graft procedures from excisional debridements by creating a new set of MS–DRGs. This would result in more accurate payment for both skin grafts and debridement. Therefore, we are proposing to remove excisional debridements (procedure code 86.22) from their current MS–DRG assignments within MS–DRGs 573 through 578 for skin grafts and assign them to new excisional debridement MS–DRGs. We are proposing to maintain MS–DRGs 573 through 578 for skin grafts. The following list describes the proposed new and revised MS–DRG titles:

Proposed new MS–DRGs based on procedure code 86.22:

- Proposed MS–DRG 570 (Skin Debridement with MCC)
- Proposed MS–DRG 571 (Skin debridement with CC)
- Proposed MS–DRG 572 (Skin Debridement without CC/MCC)

Proposed Revised MS–DRGs based on codes currently assigned to MS–DRGs 573 through 578, excluding procedure code 86.22:

- Proposed revised MS–DRG 573 (Skin Graft for Skin Ulcer or Cellulitis with MCC)
- Proposed revised MS–DRG 574 (Skin Graft for Skin Ulcer or Cellulitis with CC)
- Proposed revised MS–DRG 575 (Skin Graft for Skin Ulcer or Cellulitis without CC/MCC)
- Proposed revised MS–DRG 576 (Skin Graft Except for Skin Ulcer or Cellulitis with MCC)
- Proposed revised MS–DRG 577 (Skin Graft except for Skin Ulcer or Cellulitis with CC)
- Proposed revised MS–DRG 578 (Skin Graft Except for Skin Ulcer or Cellulitis without CC/MCC)

We welcome public comments on our proposal for FY 2012 to create three new debridement MS–DRGs 570, 571, and 572 for skin debridement and to revise MS–DRGs 573 through 578 to include skin grafts only, as indicated above.

7. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders)

a. Nutritional and Metabolic Diseases: Update of MS–DRG Titles

We received a request to revise the MS–DRG titles for MS–DRGs 640 through 642 to more clearly capture the cases that are currently assigned to these MS–DRGs. The current titles for these MS–DRGs are: MS–DRGs 640 (Nutritional & Miscellaneous Metabolic Disorders with MCC); MS–DRG 641 (Nutritional & Miscellaneous Metabolic Disorders without MCC); and MS–DRG 642 (Inborn Errors of Metabolism). The requestor suggested that we change the titles to: MS–DRG 640 (Miscellaneous Disorders of Nutrition, Metabolism, and Fluids and Electrolytes with MCC); MS–DRG 641 (Miscellaneous Disorders of Nutrition, Metabolism, and Fluids and Electrolytes without MCC); and MS–DRG 642 (Inborn and Other Disorders of Metabolism).

Our clinical advisors support these suggested changes to the titles, as the suggested changes would provide a better description of the diagnoses assigned to MS–DRGs 640, 641, and 642. Therefore, we are proposing to revise the MS–DRG titles for MS–DRGs 640, 641, and 642 as the requested suggested. We invite public comment on our proposal to change the MS–DRG titles for MS–DRGs 640, 641, and 642 for FY 2012.

b. Sleeve Gastrectomy Procedure for Morbid Obesity

Sleeve gastrectomy is a 70 percent to 80 percent greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. It may be the first step in a two-stage procedure when performing Roux-en-Y Gastric Bypass (RYGBP). Sleeve gastrectomy can be performed either as an open or a laparoscopic procedure. Sleeve gastrectomy is currently coded using ICD–9–CM procedure code 43.89 (Other total gastrectomy). Procedure code 43.89 is currently assigned to several MS–DRGs. However, the code is not assigned to MS–DRG 619, 620, or 621 (O.R. Procedures for Obesity with MCC, with CC, and without CC/MCC, respectively).

We received a request for CMS to review MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders) for consistency. Specifically, the requestor questioned why diagnosis code 278.01 (Morbid obesity), when paired on a claim with procedure code 43.89, would be assigned to MS–DRG 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, or without CC/MCC, respectively) instead of MS–DRG 619, 620, or 621.

Upon review, we determined that diagnosis code 278.01 is assigned to MDC 10. However, procedure code 43.89 is not assigned to any MS–DRG set in this MDC. Therefore, the cases are assigned to MS–DRGs 981 through 983, reflecting procedures not related to the principal diagnosis. This was an inadvertent oversight on CMS' part when the MS–DRGs were created. Therefore, we are proposing to add a procedure code or codes identifying sleeve gastrectomy to MS–DRGs 619 through 621 for FY 2012.

Currently, sleeve gastrectomy is identified in the ICD–9–CM procedure code Index as follows: Gastrectomy (partial) (subtotal) NEC 43.89. At procedure code 43.89 in the ICD–9–CM procedure code Tabular, an inclusion note identifies this code as including sleeve resection of the stomach.

In light of our proposal to add a procedure code or codes to MS–DRGs 619 through 621, we point out that there is an NCD that has precluded coverage of sleeve gastrectomy when performed either open or laparoscopically. This decision may be found in the Medicare National Coverage Determination Manual, Section 100.1, Nationally Non-Covered Indications for Bariatric Surgery for Treatment of Morbid Obesity, effective on February 12, 2009. This manual is available through the CMS Web site through a link at: *http://www.cms.gov/manuals/downloads/mcd103c1_Part2.pdf.* This manual entry affirms that treatment for obesity via use of the open or laparoscopic sleeve gastrectomy is determined to be noncovered for Medicare beneficiaries.

Noncoverage of these cases is determined by the fiscal intermediary or MAC because of the nature of procedure code 43.89, which is a code that identifies several gastrectomy procedures. Therefore, to identify a code describing many procedures in the MCE would be inappropriately restricting other procedures which are covered. However, we have received a request to create specific codes identifying both laparoscopic sleeve gastrectomy and the open procedure, vertical sleeve gastrectomy. We addressed this request at the ICD–9–CM Coordination and Maintenance Committee meeting held on March 9, 2011. Should a code or codes be created as a result of this request, we will then be able to add these codes to the MCE as a conforming noncoverage edit when combined with diagnosis code 278.01. The background information discussing sleeve gastrectomy coding can be accessed on the CMS Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticcodes/03_meetings.asp#TopOfPage.* A summary of the meeting will be available soon after the meeting is held. This summary can be found on CMS' Web site for the ICD–9–CM Coordination and Maintenance Committee at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp#TopOfPage* by scrolling down to the .pdf zip files containing the meeting agenda and handouts.

Therefore, for FY 2012, we are proposing to add a procedure code or codes identifying sleeve gastrectomy to MS–DRGs 619 through 621. However, we also intend to add any code or codes created at the ICD–9–CM Coordination and Maintenance Committee on March 9, 2011, to the MCE as sleeve gastrectomy, whether open or laparoscopic, is not covered for Medicare beneficiaries. The code or codes would appear in the "Noncovered Procedures" edit of the MCE. As the timing of the development of this proposed rule and the date of the March 2011 meeting of the ICD–9–CM Coordination and Maintenance Committee overlap, it is not possible to determine what those codes might be, or even if they will be created. However, should a code or codes be created, we propose that they will simultaneously be placed in both MS–DRGs 619 through 621 and the MCE. This decision may seem to be counterintuitive, but CMS realizes that our MS–DRGs and the Medicare GROUPER program are used for other beneficiaries and insurance plans rather than strictly for Medicare beneficiaries. A complete description of this issue will be addressed in the final rule. Any new code or codes created as a result of the ICD–9–CM Coordination and Maintenance Committee meeting will only be included in Table 6B, which will be listed in section VI. of the Addendum to the final rule and available via the Internet; we do not have a mechanism to make the codes available prior to the final rule's publication. We invite public comment on this proposal.

8. MDC 15 (Newborns and Other Neonates With Conditions Originating in the Perinatal Period): Discharge Status Code 66 (Discharged/Transferred to Critical Assess Hospital (CAH))

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50236), we finalized our transfer policy regarding transfer of patients from an acute care hospital to a CAH. In that final rule, we stated that hospitals are required to use patient discharge status code 66 on the IPPS claims to identify transfers to CAHs.

With this new requirement, a discharge from an IPPS hospital to a CAH equates to a transfer status. However, discharge status code 66 is currently not included in the MS–DRG GROUPER logic for MS–DRG 789 (Neonate, Died or Transferred to Another Acute Care Facility). Therefore, in this proposed rule, we are proposing to add discharge status code 66 to the MS–DRG GROUPER logic for MS–DRG 789. We invite public comment on our proposal to add discharge status code 66 to the MS–DRG GROUPER logic for MS–DRG 789 for FY 2012.

9. Proposed Medicare Code Editor (MCE) Changes

As explained under section II.B.1. of the preamble of this proposed rule, the Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into a MS–DRG. In this proposed rule, we discuss our intention to make the following change to the MCE edits.

In section II.G.7.a. of this preamble, we discuss that the current ICD–9–CM procedure code for sleeve gastrectomy (43.89 (Other partial gastrectomy, other)) is a noncovered code when performed for resection of the stomach in patients with morbid obesity. We also discussed that noncoverage for Medicare beneficiaries of cases containing procedure code 43.89 is determined by the fiscal intermediaries or MACs because of the nature of procedure code 43.89. This code is imprecise and identifies several other gastrectomy procedures in addition to sleeve resection. Therefore, to limit coverage by identifying a code that describes many procedures through the use of the MCE would inappropriately restrict other procedures that are covered by Medicare. In this same section, we also stated that we received a request to create specific codes identifying both laparoscopic sleeve gastrectomy and the open procedure, vertical sleeve gastrectomy. As we stated above, we addressed this request at the ICD–9–CM Coordination and Maintenance Committee meeting held on March 9, 2011. If a code or codes should be created as a result of this request, we will then be able to add these codes to the MCE as a conforming noncoverage edit when combined with diagnosis code 278.01 (Morbid obesity).

As the timing of development of this proposed rule and the holding of the ICD–9–CM Coordination and Maintenance Committee meeting on March 9, 2011 overlap, it is not possible to determine what those codes might be, or even if they will be created. However, should a code or codes be created, we propose that any code or codes for laparoscopic or open sleeve resection of the stomach be added to the MCE as a noncovered procedure or procedures, in combination with ICD–9–CM diagnosis code 278.01 (Morbid obesity). The background information discussing sleeve gastrectomy coding can be accessed on the CMS Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticcodes/03_meetings.asp#TopOfPage.* A complete description of this issue will be addressed in the final rule. Any new code or codes describing sleeve gastrectomy will only be included in Table 6B, which will be listed in section VI. of the Addendum to the final rule and available via the Internet; we do not have a mechanism to make the codes available prior to the final rule's publication. We invite public comments on this proposal.

10. Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of MS–DRG reclassification and recalibrations, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class "kidney transplant" consists of a single MS–DRG (MS–DRG 652) and the class "major bladder procedures" consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 1 and 2 and surgical class B includes MS–DRGs 3, 4, and 5. Assume also that the average costs of MS–DRG 1 is higher than that of MS–DRG 3, but the average costs of MS–DRGs 4 and 5 are higher than the average costs of MS–DRG 2. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of "other O.R. procedures" as discussed below.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the "other O.R. procedures" surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The "other O.R. procedures" class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but

are still occasionally performed on patients in the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has a lower average costs than the class ordered below it.

Based on the changes that we are proposing to make for FY 2012, as discussed in sections II.G.1. and 6. of this preamble, we are proposing to revise the surgical hierarchy for Pre-MDCs and MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue, and Breast) as follows:

In Pre-MDCs, we are proposing to reorder proposed new MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) and proposed new MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC) above MS–DRG 010 (Pancreas Transplant).

In MDC 9, we are proposing to reorder—

- MS–DRG 578 (Skin Graft Except for Skin Ulcer or Cellulitis without CC/MCC) above proposed new MS–DRG 570 (Skin Debridement with MCC);
- Proposed new MS–DRG 570 above proposed new MS–DRG 571 (Skin Debridement with CC);
- Proposed new MS–DRG 571 above proposed new MS–DRG 572 (Skin Debridement without CC/MCC; and
- Proposed new MS–DRG 572 above MS–DRG 579 (Other Skin, Subcutaneous Tissue, and Breast Procedures with MCC).

11. Complications or Comorbidity (CC) Exclusions List

a. Background

As indicated earlier in the preamble of this proposed rule, under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length of stay by at least 1 day in at least 75 percent of the patients. We refer readers to section II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47121 through 47152).

b. Proposed CC Exclusions List for FY 2012

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. As we indicated above, we developed a list of diagnoses, using physician panels, to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we have made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another.
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another.
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another.
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC.[2]

(1) Proposed Limited Revisions Based on Changes to the ICD–9–CM Diagnosis Codes

For FY 2012, we are proposing to make limited revisions to the CC Exclusions List to take into account the changes made in the ICD–9–CM diagnosis coding system effective October 1, 2011. (We refer readers to section II.G.13. of the preamble of this proposed rule for a discussion of ICD–9–CM changes.) We are proposing to make these changes in accordance with the principles established when we created the CC Exclusions List in 1987. In addition, we are indicating on the CC Exclusions List some changes as a result of updates to the ICD–9–CM codes to reflect the exclusion of codes from being MCCs under the MS–DRG system that we adopted in FY 2008.

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2012, comments and suggestions should have been submitted by early December 2010. The following comments were submitted in a timely manner, and are therefore being discussed in this section.

[2] See the FY 1989 final rule (53 FR 38485, September 30, 1988), for the revision made for the discharges occurring in FY 1989; the FY 1990 final rule (54 FR 36552, September 1, 1989), for the FY 1990 revision; the FY 1991 final rule (55 FR 36126, September 4, 1990), for the FY 1991 revision; the FY 1992 final rule (56 FR 43209, August 30, 1991) for the FY 1992 revision; the FY 1993 final rule (57 FR 39753, September 1, 1992), for the FY 1993 revision; the FY 1994 final rule (58 FR 46278, September 1, 1993), for the FY 1994 revisions; the FY 1995 final rule (59 FR 45334, September 1, 1994), for the FY 1995 revisions; the FY 1996 final rule (60 FR 45782, September 1, 1995), for the FY 1996 revisions; the FY 1997 final rule (61 FR 46171, August 30, 1996), for the FY 1997 revisions; the FY 1998 final rule (62 FR 45966, August 29, 1997) for the FY 1998 revisions; the FY 1999 final rule (63 FR 40954, July 31, 1998), for the FY 1999 revisions; the FY 2001 final rule (65 FR 47064, August 1, 2000), for the FY 2001 revisions; the FY 2002 final rule (66 FR 39851, August 1, 2001), for the FY 2002 revisions; the FY 2003 final rule (67 FR 49998, August 1, 2002), for the FY 2003 revisions; the FY 2004 final rule (68 FR 45364, August 1, 2003), for the FY 2004 revisions; the FY 2005 final rule (69 FR 49848, August 11, 2004), for the FY 2005 revisions; the FY 2006 final rule (70 FR 47640, August 12, 2005), for the FY 2006 revisions; the FY 2007 final rule (71 FR 47870) for the FY 2007 revisions; the FY 2008 final rule (72 FR 47130) for the FY 2008 revisions, the FY 2009 final rule (73 FR 48510), the FY 2010 final rule (74 FR 43799); and the FY 2011 final rule (75 FR 50114). In the FY 2000 final rule (64 FR 41490, July 30, 1999, we did not modify the CC Exclusions List because we did not make any changes to the ICD–9–CM codes for FY 2000.

a. Pressure Ulcer Diagnosis Codes

We received a comment recommending that CMS remove diagnosis codes 707.23 (Pressure ulcer, stage III) and 707.24 (Pressure ulcer, stage IV) from the CC Exclusion List when reported as a secondary diagnosis code with a principal diagnosis code for the pressure ulcer site: Diagnosis code 707.00 (Pressure ulcer, unspecified); diagnosis code 707.01 (Pressure ulcer, elbow); diagnosis code 707.02 (Pressure ulcer, upper back); diagnosis code 707.03 (Pressure ulcer, lower back); diagnosis code 707.04 (Pressure ulcer, hip); diagnosis code 707.05 (Pressure ulcer, buttock); diagnosis code 707.06 (Pressure ulcer, ankle); diagnosis code 707.07 (Pressure ulcer, heel); or diagnosis code 707.09 (Pressure ulcer, other site). Currently, when a patient is admitted with a pressure ulcer, the CC Exclusion List prevents a pressure ulcer stage diagnosis code from being designated as an MCC when reported as a secondary diagnosis. The commenter disagreed with this approach and contended that a patient admitted for treatment of a stage III or stage IV pressure ulcer likely requires resources that would qualify the case as a diagnosis with an MCC or, at a minimum, as a CC.

Our clinical advisors agree with the commenter. Therefore, we are proposing to remove diagnosis codes 707.23 and 707.24 from the CC Exclusion List when a principal diagnosis code of one of codes 707.00 through 707.09 is reported. Under this proposal, diagnosis code 707.23 or diagnosis code 707.24 would be an MCC when reported as a secondary diagnosis code with a principal diagnosis code of one of codes 707.00 through 707.09.

b. End-Stage Renal Disease Diagnosis Code

We received a suggestion from a commenter that diagnosis code 585.6 (End-stage renal disease) be added to the CC Exclusion List when reported with a principal diagnosis code of 403.90 (Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage I through stage IV, or unspecified) or diagnosis code 403.91 (Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage V or end-stage renal disease). Currently, diagnosis code 585.6 is designated as an MCC.

According to the commenter, diagnosis codes 585.6 and 403.91 are essentially the same diagnosis but coding guidelines require the reporting of two codes to identify the stage of chronic kidney disease when associated with hypertensive chronic kidney disease. The commenter suggested that there is no need for diagnosis code 585.6 to be designated as an MCC when reported with a principal diagnosis of hypertensive chronic kidney disease, stage V or end-stage renal disease. The commenter also pointed out that, while coding guidelines would preclude diagnosis codes 403.90 and 585.6 from being reported together, the MS–DRG GROUPER allows diagnosis code 585.6 to act as an MCC when reported as a secondary diagnosis with principal diagnosis code 403.90.

In response to the first issue, our clinical advisors disagree with the commenter. Diagnosis code 403.91 includes chronic kidney disease stage V or end-stage renal disease. These are two separate conditions (or stages) that are identified by two unique codes. Diagnosis code 585.5 identifies stage V chronic kidney disease and is classified as a CC. Diagnosis code 585.6 identifies end-stage renal disease, is classified as an MCC, and describes patients who require chronic dialysis. The patients diagnosed with stage V chronic kidney disease are a different population who require different resources than those patients who are diagnosed with end-stage renal disease. Therefore, we are not proposing to add diagnosis code 585.6 to the CC Exclusion List when reported with a principal diagnosis of code 403.91.

On the second issue raised by the commenter, our clinical advisors agree. Diagnosis code 403.90 identifies patients with chronic kidney disease, stages I through IV or unspecified, and diagnosis code 585.6 identifies end-stage renal disease. Our clinical advisors indicate that the reporting of diagnosis code 585.6 should not be designated as an MCC in this case. We agree with the commenter that diagnosis codes 403.90 and 585.6 should not be reported together as instructed by the Coding Guidelines. Only a code from the 585.1 through 585.4 range (stages I through IV, or unspecified) should be reported with diagnosis code 403.90. Diagnosis code 585.6 is the exclusive code that uniquely identifies end-stage renal disease and should only be reported with diagnosis code 403.91. Therefore, we are proposing to add diagnosis code 585.6 to the CC Exclusion List when reported with a principal diagnosis code of 403.90.

c. Hypertensive Chronic Kidney Disease With Chronic Kidney Disease Stage V or End-Stage Renal Disease Code

We received a comment recommending the addition of diagnosis code 403.91 (Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage V or end-stage renal disease) to the CC Exclusion List when reported as a secondary diagnosis code with principal diagnosis code 585.6 (End stage renal disease). The commenter stated that it would be unlikely that diagnosis code 403.91 would be reported as a secondary diagnosis code with diagnosis code 585.6 as the principal diagnosis code due to sequencing rules for end-stage renal disease with hypertension. Currently, diagnosis code 403.91 is designated as a CC.

Our clinical advisors agree with the commenter. Therefore, we are proposing to add diagnosis code 403.91 to the CC Exclusion List when reported as a secondary diagnosis code with principal diagnosis code 585.6.

We invite public comment on the above three proposals regarding the CC Exclusion List for FY 2012.

(2) Suggested Changes to Severity Levels for Encephalopathy

We received a request that we consider changing the following diagnosis codes from an MCC to a CC:

- 348.30 (Encephalopathy NOS)
- 348.32 (Metabolic encephalopathy)
- 348.39 (Encephalopathy NEC)
- 349.82 (Toxic encephalopathy)
- 572.2 (Hepatic encephalopathy)

For this FY 2012 IPPS/LTCH PPS proposed rule, we analyzed the claims data for the diagnosis codes mentioned above related to encephalopathy. We used the same approach we used in initially creating the MS–DRGs and classifying secondary diagnosis codes as non-CCs, CCs, or MCCs. A detailed discussion of the process and criteria we used in this process is described in the FY 2008 IPPS final rule (72 FR 47158 through 47161). We refer the readers to this discussion for complete information on our approach to developing the non-CC, CC, and MCC lists. Each diagnosis for which Medicare data were available was evaluated to determine its impact on resource use and to determine the most appropriate CC subclass (non-CC, CC, or MCC) assignment. In order to make this determination, the average cost for each subset of cases was compared to the expected cost for cases in that subset. The following format was used to evaluate each diagnosis:

Code	Diagnosis	Cnt1	C1	Cnt2	C2	Cnt3	C3

Count (Cnt) is the number of patients in each subset. C1, C2, and C3 are a measure of the impact on resource use of patients in each of the subsets. The C1, C2, and C3 values are a measure of the ratio of average costs for patients with these conditions to the expected average cost across all cases. The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is a MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is a MCC. A value close to 1.0 in the C1 field would suggest that the diagnosis code produces the same expected value as a non-CC. A value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. A value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or non-CC. For additional details on this analysis, we refer readers to the FY 2008 IPPS final rule (72 FR 47158 through 47161).

The following chart shows the analysis for each of the encephalopathy diagnosis codes that are currently classified as MCCs.

Code	Diagnosis Description	CC Level	Cnt 1	Cnt 1 Impact	Cnt 2	Cnt 2 Impact	Cnt 3	Cnt 3 Impact
34830	Encephalopathy NOS	MCC	10,082	2.1206	39,042	2.7774	60,381	3.3702
34831	Metabolic encephalopathy	MCC	6,389	2.0580	29,651	2.6952	49,343	3.4011
34839	Encephalopathy NEC	MCC	4,004	2.1118	15,003	2.7355	19,732	3.3708
34982	Toxic encephalopathy	MCC	4,333	2.3158	18,126	3.0023	26,009	3.5714
5722	Hepatic encephalopathy	MCC	1,375	1.5448	9,885	2.5054	12,421	3.4435

We ran the following data as described in FY 2008 IPPS final rule (72 FR 47158 through 47161). The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is a MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is a MCC.

The chart above shows that the C1 findings ranged from a low of 1.5448 to a high of 2.3158. As stated earlier, a C1 value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C1 findings suggest that these codes are more like a CC than a MCC. However, the C2 findings ranged from a low of 2.5054 to a high of 3.0023. Values close to 3.0 suggests the condition is more similar to an MCC than a CC or non-CC. The C2 findings support maintaining the encephalopathy codes as an MCC level. The data are clearly mixed between the C1 and C2 findings, and does not consistently support a change in the severity level. Our clinical advisers recommended that these encephalopathy codes remain at an MCC level because these patients with encephalopathy typically utilize significant resources and are at a higher severity level. Based on the clinical analysis and the lack of consistent claims data support for the severity level change, we believe that the encephalopathy codes should remain on the MCC list. Therefore, we are proposing to retain the following encephalopathy codes on the MCC list:

- 348.30 (Encephalopathy NOS)
- 348.32 (Metabolic encephalopathy)
- 348.39 (Encephalopathy NEC)
- 349.82 (Toxic encephalopathy)
- 572.2 (Hepatic encephalopathy)

We invite public comment on our proposal not to change the severity level classification for these codes.

(3) Suggested Changes to Severity Levels for Mechanical Complication and Infection Due to Device Related Codes

We received a request to change the severity classification from CCs to MCCs for the following diagnosis codes:

- 996.01 (Mechanical of cardiac device, implant and graft due to cardiac pacemaker (electrode)).
- 996.04 (Mechanical complication of cardiac device, implant, and graft due to automatic implantable cardiac defibrillator).
- 996.61 (Infection and inflammatory reaction due to internal prosthetic device, implant, and graft due to cardiac device, implant, and graft).

Currently, all three diagnosis codes are classified as a CC. For this proposed rule, we analyzed claims data using the methodology described previously in this section for these diagnosis codes. The following chart shows our findings:

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Code	Diagnosis Description	CC Level	Cnt 1	Cnt 1 Impact	Cnt 2	Cnt 2 Impact	Cnt 3	Cnt 3 Impact
99601	Malfunc cardiac pacemaker	CC	1,296	1.6723	1,920	2.4332	1,333	3.1134
99604	Mch cmp autm mplnt dfbrl	CC	419	1.7041	1,032	2.5190	660	3.1508
99661	React-cardiac dev/graft	CC	149	1.9922	633	2.8134	1,253	3.5036

We reviewed the findings from these data. The C1 findings ranged from a low of 1.6723 to a high of 1.9922. As stated earlier, a value close to 2.0 in the C1 field suggests that the condition is more like a CC than a non-CC but not as

significant in resource usage as an MCC. The C1 findings clearly support the current classification of these three codes on the CC list and the C2 findings supports this classification. Our clinical advisors agree that the data findings and their own clinical evaluation of the severity level of these conditions support the classification of these three codes on the CC list. Therefore, we are proposing that these codes remain on the CC list. We invite public comment on this proposal.

Tables 6G and 6H, Additions to and Deletions from the CC Exclusion List, respectively, which are proposed to be effective for discharges occurring on or after October 1, 2011, are not being published in the Addendum to this proposed rule because of the length of the two tables. Instead, we are making them available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS.* Each of these principal diagnoses for which there is a CC exclusion is shown in Tables 6G and 6H, which are listed in section VI. of the Addendum to this proposed rule (and available via the Internet) with an asterisk, and the conditions that will not count as a CC, are provided in an indented column immediately following the affected principal diagnosis.

A complete updated MCC, CC, and Non-CC Exclusions List is also available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS.* If finalized in this rulemaking cycle, beginning with discharges on or after October 1, 2011, the indented diagnoses will not be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

To assist readers in identifying the changes to the MCC and CC lists that occurred as a result of updates to the ICD–9–CM codes, as described in Tables 6A, 6C, and 6E, which are listed in section VI. of the Addendum to this proposed rule and available via the Internet, we are providing the following summaries of those MCC and CC changes for FY 2012.

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SUMMARY OF ADDITIONS TO THE MS-DRG MCC LIST--TABLE 6I.1

Code	Description
415.13	Saddle embolus of pulmonary artery
444.01	Saddle embolus of abdominal aorta
516.4	Lymphangioleiomyomatosis
516.61	Neuroendocrine cell hyperplasia of infancy
516.62	Pulmonary interstitial glycogenosis
516.63	Surfactant mutations of the lung
516.64	Alveolar capillary dysplasia with vein misalignment
516.69	Other interstitial lung diseases of childhood
747.31	Pulmonary artery coarctation and atresia
747.32	Pulmonary arteriovenous malformation
747.39	Other anomalies of pulmonary artery and pulmonary circulation
808.54	Multiple open pelvic fractures without disruption of pelvic circle

SUMMARY OF DELETIONS FROM THE MS-DRG MCC LIST--TABLE 6I.2

Code	Description
747.3	Anomalies of pulmonary artery

SUMMARY OF ADDITIONS TO THE MS-DRG CC LIST--TABLE 6J.1

Code	Description
286.52	Acquired hemophilia
286.53	Antiphospholipid antibody with hemorrhagic disorder
286.59	Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors
348.82	Brain death
358.30	Lambert-Eaton syndrome, unspecified
358.31	Lambert-Eaton syndrome in neoplastic disease
358.39	Lambert-Eaton syndrome in other diseases classified elsewhere
444.09	Other arterial embolism and thrombosis of abdominal aorta
516.30	Idiopathic interstitial pneumonia, not otherwise specified
516.35	Idiopathic lymphoid interstitial pneumonia
516.36	Cryptogenic organizing pneumonia
516.37	Desquamative interstitial pneumonia
516.5	Adult pulmonary Langerhans cell histiocytosis
539.01	Infection due to gastric band procedure
539.09	Other complications of gastric band procedure
539.81	Infection due to other bariatric procedure
539.89	Other complications of other bariatric procedure
596.81	Infection of cystostomy
596.82	Mechanical complication of cystostomy
596.83	Other complication of cystostomy
808.44	Multiple closed pelvic fractures without disruption of pelvic circle
996.88	Complications of transplanted organ, stem cell
997.32	Postprocedural aspiration pneumonia
997.41	Retained cholelithiasis following cholecystectomy
997.49	Other digestive system complications
999.41	Anaphylactic reaction due to administration of blood and blood products
999.42	Anaphylactic reaction due to vaccination
999.49	Anaphylactic reaction due to other serum
999.51	Other serum reaction due to administration of blood and blood products
999.52	Other serum reaction due to vaccination
999.59	Other serum reaction

SUMMARY OF DELETIONS FROM THE MS-DRG CC LIST--TABLE 6J.2

Code	Description
286.5	Hemorrhagic disorder due to intrinsic circulating anticoagulants
444.0	Embolism and thrombosis of abdominal aorta
516.3	Idiopathic fibrosing alveolitis
997.4	Digestive system complications, not elsewhere classified
999.4	Anaphylactic shock due to serum
999.5	Other serum reaction, not elsewhere classified

BILLING CODE 4120–01–C

Alternatively, the complete documentation of the GROUPER logic, including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. The current MS–DRG Definitions Manual, Version 28.0, is available on a CD for $225.00. Version 29.0 of this manual, which will include the final FY 2012 MS–DRG changes, will be available on a CD for $225.00. These manuals may be obtained by writing 3M/HIS at the following address: 100 Barnes Road, Wallingford, CT 06492; or by calling (203) 949–0303, or by obtaining an order form at the Web site: *http://www.3MHIS.com.* Please specify the revision or revisions requested.

12. Review of Procedure Codes in MS DRGs 981 Through 983; 984 Through 986; and 987 Through 989

Each year, we review cases assigned to former CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and CMS DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these CMS DRGs. Under the MS–DRGs that we adopted for FY 2008, CMS DRG 468 was split three ways and became MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 476 became MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 477 became MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

MS–DRGs 981 through 983, 984 through 986, and 987 through 989 (formerly CMS DRGs 468, 476, and 477, respectively) are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS–DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. MS–DRGs 984 through 986 (previously CMS DRG 476) are assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

- 60.0, Incision of prostate
- 60.12, Open biopsy of prostate
- 60.15, Biopsy of periprostatic tissue
- 60.18, Other diagnostic procedures on prostate and periprostatic tissue
- 60.21, Transurethral prostatectomy
- 60.29, Other transurethral prostatectomy
- 60.61, Local excision of lesion of prostate
- 60.69, Prostatectomy, not elsewhere classified
- 60.81, Incision of periprostatic tissue
- 60.82, Excision of periprostatic tissue
- 60.93, Repair of prostate
- 60.94, Control of (postoperative) hemorrhage of prostate
- 60.95, Transurethral balloon dilation of the prostatic urethra
- 60.96, Transurethral destruction of prostate tissue by microwave thermotherapy
- 60.97, Other transurethral destruction of prostate tissue by other thermotherapy
- 60.99, Other operations on prostate

All remaining O.R. procedures are assigned to MS–DRGs 981 through 983 and 987 through 989, with MS–DRGs 987 through 989 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis.[3]

Our review of MedPAR claims data showed that there were no cases that merited movement or should logically be assigned to any of the other MDCs. Therefore, for FY 2012, we are not proposing to change the procedures assigned among these MS–DRGs.

a. Moving Procedure Codes From MS–DRGs 981 Through 983 or MS–DRGs 987 Through 989 Into MDCs

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

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. As noted above, there were no cases that merited movement or that should logically be assigned to any of the other MDCs. Therefore, for FY 2012, we are not proposing to remove any procedures from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned.

b. Reassignment of Procedures Among MS–DRGs 981 Through 983, 984 Through 986, and 987 Through 989

We also annually review the list of ICD–9–CM procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, 984 through 986 (Prostatic O.R. procedure unrelated to principal diagnosis with MCC, with CC, or without CC/MCC, respectively), and 987 through 989, to ascertain whether any of those procedures should be reassigned from one of these three MS–DRGs to another of the three MS–DRGs based on average charges and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep

[3] The original list of the ICD–9–CM procedure codes for the procedures we consider nonextensive procedures, if performed with an unrelated principal diagnosis, was published in Table 6C in section IV. of the Addendum to the FY 1989 final rule (53 FR 38591). As part of the FY 1991 final rule (55 FR 36135), the FY 1992 final rule (56 FR 43212), the FY 1993 final rule (57 FR 23625), the FY 1994 final rule (58 FR 46279), the FY 1995 final rule (59 FR 45336), the FY 1996 final rule (60 FR 45783), the FY 1997 final rule (61 FR 46173), and the FY 1998 final rule (62 FR 45981), we moved several other procedures from DRG 468 to DRG 477, and some procedures from DRG 477 to DRG 468. No procedures were moved in FY 1999, as noted in the final rule (63 FR 40962); in FY 2000 (64 FR 41496); in FY 2001 (65 FR 47064); or in FY 2002 (66 FR 39852). In the FY 2003 final rule (67 FR 49999) we did not move any procedures from DRG 477. However, we did move procedure codes from DRG 468 and placed them in more clinically coherent DRGs. In the FY 2004 final rule (68 FR 45365), we moved several procedures from DRG 468 to DRGs 476 and 477 because the procedures are nonextensive. In the FY 2005 final rule (69 FR 48950), we moved one procedure from DRG 468 to 477. In addition, we added several existing procedures to DRGs 476 and 477. In the FY 2006 (70 FR 47317), we moved one procedure from DRG 468 and assigned it to DRG 477. In FY 2007, we moved one procedure from DRG 468 and assigned it to DRGs 479, 553, and 554. In FYs 2008, 2009, FY 2010, and FY 2011, no procedures were moved, as noted in the FY 2008 final rule with comment period (72 FR 46241), the FY 2009 final rule (73 FR 48513), the FY 2010 final rule (74 FR 43796); and the FY 2011 final rule (75 FR 50122).

the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

There were no cases representing shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical, or that merited movement so that cases should logically be assigned to any of the other MDCs. Therefore, for FY 2012, we are not proposing to move any procedure codes among these MS–DRGs.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on the review of cases in the MDCs as described above in sections III.G.12.a. and b., we are not proposing to add any diagnosis or procedure codes to MDCs for FY 2012.

13. Changes to the ICD–9–CM Coding System, Including Discussion of the Replacement of the ICD–9–CM Coding System With the ICD–10–CM and ICD–10–PCS Systems in FY 2014

a. ICD–9–CM Coding System

As described in section II.B.1. of the preamble of this proposed rule, the ICD–9–CM is a coding system currently used for the reporting of diagnoses and procedures performed on a patient. In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention, and CMS, charged with maintaining and updating the ICD–9–CM system. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD–9–CM to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The Official Version of the ICD–9–CM contains the list of valid diagnosis and procedure codes. (The Official Version of the ICD–9–CM is available from the Government Printing Office on CD–ROM for $19.00 by calling (202) 512–1800.) Complete information on ordering the CD–ROM is also available at: *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/05_CDROM.asp#TopOfPage.* The Official Version of the ICD–9–CM is no longer available in printed manual form from the Federal Government; it is only available on CD–ROM. Users who need a paper version are referred to one of the many products available from publishing houses.

The NCHS has lead responsibility for the ICD–9–CM diagnosis codes included in the *Tabular List* and *Alphabetic Index for Diseases,* while CMS has lead responsibility for the ICD–9–CM procedure codes included in the *Tabular List* and *Alphabetic Index for Procedures.*

The Committee encourages participation in the above process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2012 at a public meeting held on September 15–16, 2010 and finalized the coding changes after consideration of comments received at the meetings and in writing by November 19, 2010. Those coding changes are announced in Tables 6A through 6F, which are listed in section VI. of the Addendum to this proposed rule and available via the Internet.

The Committee held its 2011 meeting on March 9–10, 2011. New codes for which there was a consensus of public support and for which complete tabular and indexing changes are made by May 2011 will be included in the October 1, 2011 update to ICD–9–CM. Code revisions that were discussed at the March 9–10, 2011 Committee meeting but that could not be finalized in time to include them in the tables listed in section VI. of the Addendum to this proposed rule will be included in Tables 6A through 6F, which will be listed in section VI. of the Addendum to the final rule and available via the Internet, and will be marked with an asterisk (*).

Copies of the minutes of the procedure codes discussions at the Committee's September 15–16, 2010 meeting and March 9–10, 2011 meeting can be obtained from the CMS Web site at: *http://cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp.* The minutes of the diagnosis codes discussions at the September 15–16, 2010 meeting and March 9–10, 2011 meeting are found at: *http://www.cdc.gov/nchs/icd.htm.* These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–9–CM Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by E-mail to: *dfp4@cdc.gov.*

Questions and comments concerning the procedure codes should be addressed to: Patricia E. Brooks, Co-Chairperson, ICD–9–CM Coordination and Maintenance Committee, CMS, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. Comments may be sent by E-mail to: *patricia.brooks2@cms.hhs.gov.*

The ICD–9–CM code changes that have been approved will become effective October 1, 2011. The new ICD–9–CM codes are listed, along with their MS–DRG classifications, in Tables 6A and 6B (New Diagnosis Codes and New Procedure Codes, respectively), which are listed in section VI. of the Addendum to this proposed rule and available via the Internet. As we stated above, the code numbers and their titles were presented for public comment at the ICD–9–CM Coordination and Maintenance Committee meetings. Both oral and written comments were considered before the codes were approved.

In this proposed rule, we are soliciting comments on the proposed classification of these new codes, which are shown in Tables 6A and 6B listed in section VI. of the Addendum to this proposed rule and available via the Internet.

For codes that have been replaced by new or expanded codes, the corresponding new or expanded diagnosis codes are included in Table 6A, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet. New

procedure codes are shown in Table 6B, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet. Diagnosis codes that have been replaced by expanded codes or other codes or have been deleted are in Table 6C (Invalid Diagnosis Codes), which is listed in section VI. of the Addendum to this proposed rule and available via the Internet. These invalid diagnosis codes will not be recognized by the GROUPER beginning with discharges occurring on or after October 1, 2011. Table 6D, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet contains invalid procedure codes. These invalid procedure codes will not be recognized by the GROUPER beginning with discharges occurring on or after October 1, 2011. Revisions to diagnosis code titles are in Table 6E (Revised Diagnosis Code Titles), which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, and also includes the MS–DRG assignments for these revised codes. Table 6F, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet includes revised procedure code titles for FY 2012.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October. As stated previously, ICD–9–CM codes discussed at the March 9–10, 2011 Committee meeting that received consensus and that are finalized by May 2011 will be included in Tables 6A through 6F, which will be listed in section VI. of the Addendum to the final rule and available via the Internet.

Section 503(a) of Public Law 108–173 included a requirement for updating ICD–9–CM codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the "Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) * * * until the fiscal year that begins after such date." This requirement improves the recognition of new technologies under the IPPS system by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD–9–CM Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the ICD–9–CM Coordination and Maintenance Committee meeting if the request is received at least 2 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS Web site. The public decides whether or not to attend the meeting based on the topics listed on the agenda. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. A complete addendum describing details of all changes to ICD–9–CM, both tabular and index, is published on the CMS and NCHS Web sites in May of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this new April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–9–CM Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were no requests approved for an expedited April l, 2011 implementation of an ICD–9–CM code at the September 15–16, 2010 Committee meeting. Therefore, there were no new ICD–9–CM codes implemented on April 1, 2011.

Current addendum and code title information is published on the CMS Web site at: *http://www.cms.hhs.gov/icd9ProviderDiagnosticCodes/01_overview.asp#TopofPage.* Information on ICD–9–CM diagnosis codes, along with the Official ICD–9–CM Coding Guidelines, can be found on the Web site at: *http://www.cdc.gov/nchs/icd9.htm.* Information on new, revised, and deleted ICD–9–CM codes is also provided to the AHA for publication in the *Coding Clinic for ICD–9–CM.* AHA also distributes information to publishers and software vendors.

CMS also sends copies of all ICD–9–CM coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

These same means of disseminating information on new, revised, and deleted ICD–9–CM codes will be used to notify providers, publishers, software vendors, contractors, and others of any changes to the ICD–9–CM codes that are implemented in April. The code titles

are adopted as part of the ICD–9–CM Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules. We will continue to publish the October code updates in this manner within the IPPS proposed and final rules. For codes that are implemented in April, we will assign the new procedure code to the same MS–DRG in which its predecessor code was assigned so there will be no MS–DRG impact as far as MS–DRG assignment. Any midyear coding updates will be available through the Web sites indicated above and through the *Coding Clinic for ICD–9–CM.* Publishers and software vendors currently obtain code changes through these sources in order to update their code books and software systems. We will strive to have the April 1 updates available through these Web sites 5 months prior to implementation (that is, early November of the previous year), as is the case for the October 1 updates.

b. Code Freeze

The International Classification of Diseases, 10th Revision (ICD–10) coding system applicable to hospital inpatient services will be implemented on October 1, 2013, as described in the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS final rule (74 FR 3328 through 3362, January 16, 2009). The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the Official ICD–10–CM and ICD–10–PCS Guidelines for Coding and Reporting. In the January 16, 2009 ICD–10–CM and ICD–10–PCS final rule (74 FR 3328 through 3362), there was a discussion of the need for a partial or total freeze in the annual updates to both ICD–9–CM and ICD–10–CM and ICD–10–PCS codes. The public comment addressed in that final rule stated that the annual code set updates should cease l year prior to the implementation of ICD–10. The commenters stated that this freeze of code updates would allow for instructional and/or coding software programs to be designed and purchased early, without concern that an upgrade would take place immediately before the compliance date, necessitating additional updates and purchases.

We responded to comments in the ICD–10 final rule that the ICD–9–CM Coordination and Maintenance Committee has jurisdiction over any action impacting the ICD–9–CM and ICD–10 code sets. Therefore, we indicated that the issue of consideration of a moratorium on updates to the ICD–9–CM, ICD–10–CM, and ICD–10–PCS code sets in anticipation of the adoption of ICD–10–CM and ICD–10–PCS would be addressed through the Committee at a future public meeting.

The code freeze was discussed at multiple meetings of the ICD–9–CM Coordination and Maintenance Committee and public comment was actively solicited. The Committee evaluated all comments from participants attending the Committee meetings as well as written comments that were received. There was an announcement at the September 15–16, 2010 ICD–9–CM Coordination and Maintenance Committee meeting that a partial freeze of both ICD–9–CM and ICD–10 codes would be implemented as follows:

- The last regular annual update to both ICD–9–CM and ICD–10 code sets will be made on October 1, 2011.
- On October 1, 2012, there will be only limited code updates to both ICD–9–CM and ICD–10 code sets to capture new technology and new diseases.
- There will be no updates to ICD–9–CM on October 1, 2013, as the system will no longer be a HIPAA standard. There will be only limited code updates to ICD–10 code sets on October 1, 2013, to capture new technology and new diseases.
- On October 1, 2014, regular updates to ICD–10 will begin.

The ICD–9–CM Coordination and Maintenance Committee announced that it would continue to meet twice a year during the freeze. At these meetings, the public will be encouraged to comment on whether or not requests for new diagnosis and procedure codes should be created based on the need to capture new technology and new diseases. Any code requests that do not meet the criteria will be evaluated for implementation within ICD–10 on or after October 1, 2014, once the partial freeze is ended.

Complete information on the partial code freeze and discussions of the issues at the Committee meetings can be found on the ICD–9–CM Coordination and Maintenance Committee Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03.* A summary of the September 15–16, 2010 Committee meeting, along with both written and audio transcripts of this meeting, are posted on the "Download" section of this Web page.

c. Processing of 25 Diagnosis Codes and 25 Procedure Codes on Hospital Inpatient Claims

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127), we discussed that we had received repeated requests from the hospital community to process all 25 diagnosis codes and 25 procedure codes submitted on electronic hospital inpatient claims. Prior to January 1, 2011, hospitals could submit up to 25 diagnoses and 25 procedures; however, CMS' system limitations allowed for the processing of only the first 9 diagnoses and 6 procedures. We indicated in that final rule that, as part of our efforts to update Medicare systems prior to the implementation of ICD–10 on October 1, 2013, we were undergoing extensive system updates as part of the move to 5010, which includes the ability to accept ICD–10 codes. This complicated transition involved converting many internal systems prior to October 1, 2013, when ICD–10 will be implemented. We stated that, as one important step in this planned conversion process, we were planning to complete the expansion of our internal system capability so that we are able to process up to 25 diagnoses and 25 procedures on hospital inpatient claims as part of the HIPAA ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards system update. We have not completed this expansion, and, as a result, we were able to process up to 25 diagnosis codes and 25 procedure codes when received on the 5010 format starting on January 1, 2011. We continue to recognize the value of the additional information provided by this coded data for multiple uses such as for payment, quality measures, outcome analysis, and other important uses.

d. ICD–10 MS–DRGs

In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received comments on the creation of the ICD–10 version of the MS–DRGs, which will be implemented on October 1, 2013 (FY 2014) when we implement the reporting of ICD–10 codes (75 FR 50127 and 50128). While we did not propose an ICD–10 version of the MS–DRGs in the FY 2011 IPPS/LTCH PPS proposed rule, we noted that we have been actively involved in converting our current MS–DRGs from ICD–9–CM codes to ICD–10 codes and sharing this information through the ICD–9–CM Coordination and Maintenance Committee. We undertook this early conversion project

to assist other payers and providers in understanding how to go about their own conversion projects. We posted ICD–10 MS–DRGs based on V26.0 (FY 2009) of the MS–DRGs. We also posted a paper that describes how CMS went about completing this project and suggestions for others to follow. All of this information can be found on the CMS Web site at: *http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp.* We have continued to keep the public updated on our maintenance efforts for ICD–10–CM and ICD–10–PCS coding systems as well as the General Equivalence Mappings that assist in conversion through the ICD–9–CM Coordination and Maintenance Committee. Information on these committee meetings can be found at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp.*

During FY 2011, we developed and posted Version 28.0 of the ICD–10 MS–DRGs based on the FY 2011 MS–DRGs (Version 28.0) that we finalized in the FY 2011 IPPS/LTCH PPS final rule on the CMS Web site. This ICD–10 MS–DRG Version 28.0 also includes the CC Exclusion List and the ICD–10 version of the hospital acquired conditions (HACs), which was not posted with Version 26.0. We also discussed this update at the September 15–16, 2010 and the March 9–10, 2011 meetings of the ICD–9–CM Coordination and Maintenance Committee. The minutes of these two meetings are posted on the CMS Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp.* We will continue to work with the public to explain how we are approaching the conversion of MS–DRGs to ICD–10 and will post drafts of updates as they are developed for public review. The final version of the ICD–10 MS–DRGs to be implemented in FY 2014 will be subject to notice and comment rulemaking. In the meantime, we will provide extensive and detailed information on this activity through the ICD–9–CM Coordination and Maintenance Committee.

14. Other Issues

a. O.R./Non-O.R. Status of Procedures

(1) Brachytherapy Code

We received a request that we add ICD–9–CM procedure code 92.27 (Implantation or Insertion of Radioactive Elements) [Brachytherapy] into 41 MS–DRGs that are listed below:

- 129 (Major Head and Neck Procedures with CC/MCC or Major Device)
- 130 (Major Head and Neck Procedures without CC/MCC)
- 163 (Major Chest Procedures with MCC)
- 164 (Major Chest Procedures with CC)
- 165 (Major Chest Procedures without CC/MCC)
- 180 (Respiratory Neoplasms with MCC)
- 181 (Respiratory Neoplasms with CC)
- 182 (Respiratory Neoplasms without CC/MCC)
- 326 (Stomach, Esophageal and Duodenal Procedures with MCC)
- 327 (Stomach, Esophageal and Duodenal Procedures with CC)
- 328 (Stomach, Esophageal and Duodenal Procedures without CC/MCC)
- 329 (Major Small and Large Bowel Procedures with MCC)
- 330 (Major Small and Large Bowel Procedures with CC)
- 331 (Major Small and Large Bowel Procedures without CC/MCC)
- 332 (Rectal Resection with MCC)
- 333 (Rectal Resection with CC)
- 334 (Rectal Resection without CC/MCC)
- 344 (Minor Small and Large Bowel Procedures with MCC)
- 345 (Minor Small and Large Bowel Procedures with CC)
- 346 (Minor Small and Large Bowel Procedures without CC/MCC)
- 347 (Anal and Stomal Procedures with MCC)
- 348 (Anal and Stomal Procedures with CC)
- 349 (Anal and Stomal Procedures without CC/MCC)
- 405 (Pancreas, Liver and Shunt Procedures with MCC)
- 406 (Pancreas, Liver and Shunt Procedures with CC)
- 407 (Pancreas, Liver and Shunt Procedures without CC/MCC)
- 490 (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator)
- 491 (Back and Neck Procedures Except Spinal Fusion without CC/MCC)
- 500 (Soft Tissue procedures with MCC)
- 501 (Soft Tissue procedures with CC)
- 502 (Soft Tissue procedures without CC/MCC)
- 584 (Breast Biopsy, Local Excision and Other Breast Procedures with CC/MCC)
- 585 (Breast Biopsy, Local Excision and Other Breast Procedures without CC/MCC)
- 597 (Malignant Breast Disorders with MCC)
- 598 (Malignant Breast Disorders with CC)
- 599 (Malignant Breast Disorders without CC/MCC)
- 653 (Major Bladder Procedures with MCC)
- 654 (Major Bladder Procedures with CC)
- 655 (Major Bladder Procedures without CC/MCC)
- 656 (Kidney and Ureter Procedures for Neoplasm with MCC)
- 657 (Kidney and Ureter Procedures for Neoplasm with CC)
- 658 (Kidney and Ureter Procedures for Neoplasm without CC/MCC)
- 662 (Minor Bladder Procedures with MCC)
- 663 (Minor Bladder Procedures with CC)
- 664 (Minor Bladder Procedures without CC/MCC)
- 668 (Transurethral Procedures with MCC)
- 669 (Transurethral Procedures with CC)
- 670 (Transurethral Procedures without CC/MCC)
- 671 (Urethral Procedures with CC/MCC)
- 672 (Urethral Procedures without CC/MCC)
- 707 (Major Male Pelvic Procedures with CC/MCC)
- 708 (Major Male Pelvic Procedures without CC/MCC)
- 736 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC)
- 737 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with CC)
- 738 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy without CC/MCC)
- 739 (Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with MCC)
- 740 (Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with CC)
- 741 (Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy without CC/MCC)
- 746 (Vagina, Cervix and Vulva Procedures with CC/MCC)
- 747 (Vagina, Cervix and Vulva Procedures without CC/MCC)
- 748 (Female Reproductive System Reconstructive Procedures)
- 749 (Other Female Reproductive System O.R. Procedures with CC/MCC)
- 750 (Other Female Reproductive System O.R. Procedures without CC/MCC)

We examined MedPAR claims data on this request and only found 150 cases throughout these MS–DRGs. Our findings are presented in the table below.

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MS-DRG with Code 92.27				MS-DRG without Code 92.27		
DRG	Number of Cases	Average Length of Stay	Average Costs	Number of Cases	Average Length of Stay	Average Costs
129	6	6.67	$15,793	1,326	5.35	$14,400
130	2	1.00	$7,587	904	2.78	$7,860
163	17	8.18	$24,166	11,871	13.90	$31,860
164	52	5.94	$17,505	16,487	7.13	$16,865
165	41	2.95	$10,638	9,260	4.27	$11,754
180	0	0	0	19,304	7.37	$11,396
181	0	0	0	22,205	5.30	$8,014
182	0	0	0	2,365	3.59	$5,580
326	0	0	0	10,321	15.48	$35,437
327	1	4.00	$9,302	9.671	8.67	$17,889
328	0	0	0	8,461	3.49	$9,161
329	1	24.00	$37,654	41,107	15.10	$33,003
330	2	9.00	$20,043	53,584	8.91	$16,736
331	0	0	0	22,105	5.13	$10,654
332	1	48.00	$61,169	1,439	13.40	$29,727
333	1	10.00	$11,446	4,494	7.86	$16,008
334	1	16.00	$27,312	2,855	4.76	$10,518
344	0	0	0	756	11.30	$21,590
345	0	0	0	2,906	6.67	$11,190
346	0	0	0	2,331	4.52	$7,757
347	0	0	0	1,430	8.80	$16,644
348	0	0	0	3,975	5.40	$9,326
349	0	0	0	3,512	2.75	$5,311
405	1	8.00	$8,444	3,940	15.45	$35,970
406	2	10.50	$23,231	4,749	7.83	$17,333
407	0	0	0	1,799	8.04	$12,148
490	0	0	0	19,840	4.24	$11,940
491	0	0	0	38,574	2.05	$6,794
500	0	0	0	1,935	10.86	$20,600
501	5	7.00	$12,896	4,961	5.77	$10,256
502	5	7.40	$13,876	5,009	2.78	$6,844
584	0	0	0	790	5.32	$11,126
585	0	0	0	1,318	2.12	$7,283
597	0	0	0	532	7.41	$10,990
598	0	0	0	1,369	5.32	$7,624
599	0	0	0	165	3.26	$4,368
653				1,589	16.34	$35,856
654				3,502	9.13	$19,367
655	0	0	0	1,121	5.53	$413,162
656	1	20.00	$77,737	3,110	10.00	$24,022
657	0	0	0	7,885	5.63	$13,345

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The numbers of cases in any of the MS–DRGs listed were minimal. Many of the MS–DRGs listed had no occurrences of procedure code 92.27. The highest number of cases found was 52, in MS–DRG 164 (Major Chest Procedures with CC). Based on these findings, we do not believe that making a MS–DRG change based on such a minimal number of cases can be justified. Therefore, we are proposing not to add procedure code 92.27 to any of the 41 MS–DRGs listed above. Further, we are not proposing any MS–DRG changes for procedure code 92.27. We welcome public comment on our proposal not to make changes to procedure code 92.27.

(2) Intraoperative Electron Radiation Therapy (IOERT)

MS-DRG with Code 92.27				MS-DRG without Code 92.27		
DRG	Number of Cases	Average Length of Stay	Average Costs	Number of Cases	Average Length of Stay	Average Costs
658	0	0	0	6,150	3.25	$9,718
662	0	0	0	763	10.21	$19,455
663	0	0	0	1,818	2.18	$9,729
664	0	0	0	2,705	1.86	$7,457
668	2	3.50	$3,972	2,908	8.99	$16,852
669	4	6.50	$7,832	13,776	4.25	$8,398
670	2	1.50	$5,639	7,321	2.24	$5,158
671	0	0	0	746	5.45	$9,778
672	0	0	0	613	2.31	$5,575
707	0	0	0	4,719	4.26	$12,080
708	1	3.00	$11,252	14,329	1.80	$8,572
736	0	0	0	775	13.18	$29,827
737	1	6.00	$13,045	2,844	6.49	$13,348
738	0	0	0	642	3.47	$7,966
739	0	0	0	790	10.18	$23,070
740	0	0	0	3,914	4.34	$10,214
741	1	1.00	$3,225	4,917	2.31	$7,438
746	0	0	0	2,282	3.97	$8,504
747	0	0	0	6,243	1.72	$5,995
748	0	0	0	14,682	1.67	$6,285
749	0	0	0	920	8.58	$16,781
750	0	0	0	285	2.88	$7,116

We received a public comment that was outside of the scope of the FY 2011 IPPS/LTCH PPS proposed rule regarding the MS–DRG assignment for intraoperative electron radiation therapy (IOERT). This issue was discussed briefly in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50128). However, we are addressing this issue in this FY 2012 proposed rule. IOERT is the direct application of radiation to a tumor and/or tumor bed while the patient is undergoing surgery for cancer. This technology may be used for cancers of the rectum, head/neck, pancreas, lung, genitourinary, soft tissue, and breast. IOERT is a secondary procedure performed during the primary tumor removal surgery.

The commenter requested that CMS update the MS–DRG assignments for procedure code 92.41 (Intraoperative electron radiation therapy) to ensure that the cost of this technology is captured in each MS–DRG involving tumor removal in the rectum, head/neck, pancreas, lung, genitourinary, soft tissue, and breast. Currently, this code is not assigned to a specific MS–DRG as the primary procedure performed, the tumor removal, would determine the appropriate MS–DRG assignment.

The commenter provided a recommended list of MS–DRGs to which IOERT should be assigned:

MS-DRG	Description
129	Major Head and Neck Procedures with CC/MCC or Major Device
130	Major Head and Neck Procedures without CC/MCC
133	Other Ear, Nose, Mouth and Throat O,R, Procedures with CC/MCC
134	Other Ear, Nose, Mouth and Throat O.R. Procedures without CC/MCC
163	Major Chest Procedures with MCC
164	Major Chest Procedures with CC
165	Major Chest Procedures without CC/MCC
166	Other Respiratory System O.R. Procedures with MCC
167	Other Respiratory System O.R. Procedures with CC
168	Other Respiratory System O,R Procedures without CC/MCC
326	Stomach, Esophageal and Duodenal Procedures with MCC
327	Stomach, Esophageal and Duodenal Procedures with CC
328	Stomach, Esophageal and Duodenal Procedures without CC/MCC
329	Major Small and Large Bowel Procedures with MCC
330	Major Small and Large Bowel Procedures with CC
331	Major Small and Large Bowel Procedures without CC/MCC
332	Rectal Resection with MCC
333	Rectal Resection with CC
334	Rectal Resection without CC/MCC
344	Minor Small and Large Bowel Procedures with MCC
345	Minor Small and Large Bowel Procedures with CC
346	Minor Small and Large Bowel Procedures without CC/MCC
347	Anal and Stomal Procedures with MCC
348	Anal and Stomal Procedures with CC
349	Anal and Stomal Procedures without CC/MCC
356	Other Digestive System O.R. Procedures with MCC
357	Other Digestive System O.R. Procedures with CC
358	Other Digestive System O,R, Procedures without CC/MCC
405	Pancreas, Liver and Shunt Procedures with MCC
406	Pancreas, Liver and Shunt Procedures with CC
407	Pancreas, Liver and Shunt Procedures without CC/MCC
490	Back and Neck Procedures Except Spinal Fusion with CC/MCC
491	Back and Neck Procedures Except Spinal Fusion without CC/MCC
500	Soft Tissue Procedures with MCC
501	Soft Tissue Procedures with CC
502	Soft Tissue Procedures without CC/MCC
579	Other Skin, Subcutaneous Tissue and Breast Procedures with MCC
580	Other Skin, Subcutaneous Tissue and Breast Procedures with CC
58 1	Other Skin, Subcutaneous Tissue and Breast Procedures without CC/MCC
584	Breast Biopsy, Local Excision and Other Breast Procedures with CC/MCC
585	Breast Biopsy, Local Excision and Other Breast Procedures without

MS-DRG	Description
	CC/MCC
653	Major Bladder Procedures with MCC
654	Major Bladder Procedures with CC
655	Major Bladder Procedures without CC/MCC
656	Kidney and Ureter Procedures For Neoplasm with MCC
657	Kidney and Ureter Procedures For Neoplasm with CC
658	Kidney and Ureter Procedures for Neoplasm without MCC/CC
662	Minor Bladder Procedures with MCC
663	Minor Bladder Procedures with CC
664	Minor Bladder Procedures without CC/MCC
668	Transurethral Procedures with MCC
669	Transurethral Procedures with CC
670	Transurethral Procedures without CC/MCC
671	Urethral Procedures with CC/MCC
672	Urethral Procedures without CC/MCC
707	Major Male Pelvic Procedures with CC/MCC
708	Major Male Pelvic Procedures without CC/MCC
715	Other Male Reproductive System O.R. Procedures For Malignancy with CC/MCC
716	Other Male Reproductive System O.R. Procedures For Malignancy without CC/MCC
736	Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC
737	Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with CC
738	Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy without CC/MCC
739	Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with MCC
740	Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy with CC
741	Uterine and Adnexa Procedures for Nonovarian or Adnexal Malignancy without CC/MCC
746	Vagina, Cervix and Vulva Procedures with CC/MCC
747	Vagina Cervix and Vulva Procedures without CC/MCC
748	Female Reproductive System Reconstructive Procedures
749	Other Female Reproductive System O.R. Procedures with CC/MCC
750	Other Female Reproductive System O.R. Procedures without CC/MCC

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Based on our review of the FY 2010 MedPAR claims data, we found a total of 12 cases with procedure code 92.41 reported. There were three cases assigned to MS–DRG 502; two cases each assigned to two different MS–DRGs: MS–DRG 333 and MS–DRG 501; and one case assigned each to five MS–DRGs: MS–DRGs 130, 168, 327, 329, and 330.

The IOERT cases were assigned to an MS–DRG that included the tumor removal of that particular site, which was listed on the table above. Therefore, the cost of this technology is appropriately identified in the MS–DRG assignment for the removal of the tumor by specific site, and no change is warranted at this time. Therefore, we are not proposing any changes to the assignment for IOERT cases. We invite public comment on our proposal to not change the assignment for IOERT cases for FY 2012.

b. IPPS Recalled Device Policy Clarification

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that has been recalled determined the base MS–DRG assignment. At that time, we specified that we would reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit equal to 50 percent or more of the cost of the device when a manufacturer provided a credit for a recalled device.

A similar policy was adopted under the Outpatient Prospective Payment System (OPPS) in CY 2008 (the "partial credit" policy). This policy can be viewed in its entirety at 72 FR 66743 though 66748. In general terms, under the partial credit policy, CMS reduces the amount of payment for an implanted device made under the OPPS for which CMS determines that a significant portion of the payment is attributable to the cost of an implanted device when the provider receives partial credit for the cost of a replaced device, but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the new replacement device being implanted.

It has come to our attention that there is a discrepancy between the IPPS policy and the OPPS partial credit policy for replacement devices. In particular, the OPPS partial credit policy specifies that the credit must be 50 percent or greater of the cost of the replacement device. However, the IPPS policy does not specify whether the credit should be 50 percent or greater of the replacement device or the original device. We believe that the OPPS partial credit policy and the IPPS policy should be consistent with each other on the issue of whether the 50 percent or more credit is with respect to the replacement device or the original device. Therefore, we are proposing to clarify the IPPS policy to state that the policy applies where "the hospital received a credit equal to 50 percent or more of the cost of the replacement device." We invite public comment on this proposal.

H. Recalibration of MS–DRG Weights

In developing the proposed FY 2012 system of weights, we used two data sources: Claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2010 MedPAR data used in this proposed rule include discharges occurring on October 1, 2009, through September 30, 2010, based on bills received by CMS through December 31, 2010, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which are under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2010 MedPAR file used in calculating the proposed relative weights includes data for approximately 10,814,950 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR "GHO Paid" indicator field on the claim record is equal to "1" or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR "Indirect Medical Education (IME)" payment field, indicating that the claim was an "IME only" claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. The second data source used in the cost-based relative weighting methodology is the FY 2009 Medicare cost report data files from HCRIS (that is, cost reports beginning on or after October 1, 2008, and before October 1, 2009), which represents the most recent full set of cost report data available. We used the December 31, 2010 update of the HCRIS cost report files for FY 2009 in setting the relative cost-based weights.

The methodology we used to calculate the DRG cost-based relative weights from the FY 2010 MedPAR claims data and FY 2009 Medicare cost report data is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2012 MS–DRG classifications discussed in sections II.B. and G. of the preamble of this proposed rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2010 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.
- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $10.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, special equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood charges, and anesthesia charges were also deleted.
- At least 96.2 percent of the providers in the MedPAR file had charges for 10 of the 15 cost centers. Claims for providers that did not have charges greater than zero for at least 10 of the 15 cost centers were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA

indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to "Y" for "Yes" for all claims that otherwise have an "N" (No) or a "U" (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a "Y" indicator is associated with the diagnosis on the claim), then it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an "N" indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HACs are likely to be higher as well. Thus, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to "Y" only for relative weight-setting purposes for all claims that otherwise have a "N" or an "U" in the POA field. This resetting "forced" the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

Once the MedPAR data were trimmed and the statistical outliers were removed, the charges for each of the 15 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 15 cost groups so that each MS–DRG had 15 standardized charge totals. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2009 cost report data.

The 15 cost centers that we used in the relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the 15 national cost center CCRs.

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Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4)	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number)	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number)	Medicare Charges from HCRIS (Worksheet D-4, Column & line number)
Routine Days	Private Room Charges	011X and 014X		Adults & Pediatrics (General Routine Care)	C_1_C5_25	C_1_C6_25	D4_HOS_C2_25
	Semi-Private Room Charges	010X, 012X, 013X and 016X-019X				C_1_C7_25	D4_HOS_C2_26
	Ward Charges	015X					
Intensive Days	Intensive Care Charges	020X		Intensive Care Unit	C_1_C5_26	C_1_C6_26	D4_HOS_C2_26
						C_1_C7_26	
	Coronary Care Charges	021X		Coronary Care Unit	C_1_C5_27	C_1_C6_27	D4_HOS_C2_27
						C_1_C7_27	
				Burn Intensive Care Unit	C_1_C5_28	C_1_C6_28	D4_HOS_C2_28
						C_1_C7_28	
				Surgical Intensive Care Unit	C_1_C5_29	C_1_C6_29	D4_HOS_C2_29
						C_1_C7_29	
				Other Special Care Unit	C_1_C5_30	C_1_C6_30	D4_HOS_C2_30
						C_1_C7_30	
Drugs	Pharmacy Charges	025X, 026X and 063X		Intravenous Therapy	C_1_C5_48	C_1_C6_48	D4_HOS_C2_48

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4)	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number)	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number)	Medicare Charges from HCRIS (Worksheet D-4, Column & line number)
						C_1_C7_48	
				Drugs Charged To Patient	C_1_C5_56	C_1_C6_56	D4_HOS_C2_56
						C_1_C7_56	
Supplies and Equipment	Medical/Surgical Supply Charges	027X and 062X		Medical Supplies Charged to Patients	C_1_C5_55	C_1_C6_55	D4_HOS_C2_55
						C_1_C7_55	
	Durable Medical Equipment Charges	0290, 0291, 0292 and 0294-0299		DME-Rented	C_1_C5_66	C_1_C6_66	D4_HOS_C2_66
						C_1_C7_66	
	Used Durable Medical Charges	0293		DME-Sold	C_1_C5_67	C_1_C6_67	D4_HOS_C2_67
						C_1_C7_67	
Therapy Services	Physical Therapy Charges	042X		Physical Therapy	C_1_C5_50	C_1_C6_50	D4_HOS_C2_50
						C_1_C7_50	
	Occupational Therapy Charges	043X		Occupational Therapy	C_1_C5_51	C_1_C6_51	D4_HOS_C2_51
						C_1_C7_51	
	Speech Pathology Charges	044X and 047X		Speech Pathology	C_1_C5_52	C_1_C6_52	D4_HOS_C2_52
						C_1_C7_52	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4)	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number)	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number)	Medicare Charges from HCRIS (Worksheet D-4, Column & line number)
Inhalation Therapy	Inhalation Therapy Charges	041X and 046X		Respiratory Therapy	C_1_C5_49	C_1_C6_49	D4_HOS_C2_49
						C_1_C7_49	
Operating Room	Operating Room Charges	036X, 071X and 072X		Operating Room	C_1_C5_37	C_1_C6_37	D4_HOS_C2_37
For all DRGs but Labor & Delivery						C_1_C7_37	
				Recovery Room	C_1_C5_38	C_1_C6_38	D4_HOS_C2_38
						C_1_C7_38	
Labor & Delivery	Operating Room Charges	036X, 071X and 072X		Delivery Room and Labor Room	C_1_C5_39	C_1_C6_39	D4_HOS_C2_39
ONLY FOR THE 6 Labor & Delivery DRGs						C_1_C7_39	
370, 371, 372, 373, 374, 375	Clinic Charges	051X		Obstetrics Clinic	C_1_C5_63	C_1_C6_63	D4_HOS_C2_63
						C_1_C7_63	
Anesthesia	Anesthesia Charges	037X		Anesthesi-ology	C_1_C5_40	C_1_C6_40	D4_HOS_C2_40
						C_1_C7_40	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4)	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number)	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number)	Medicare Charges from HCRIS (Worksheet D-4, Column & line number)
Cardiology	Cardiology Charges	048X and 073X		Electro-cardiology	C_1_C5_53	C_1_C6_53	D4_HOS_C2_53
						C_1_C7_53	
Laboratory	Laboratory Charges	030X, 031X, 074X and 075X		Laboratory	C_1_C5_44	C_1_C6_44	D4_HOS_C2_44
						C_1_C7_44	
				PBP Clinic Laboratory Services	C_1_C5_45	C_1_C6_45	D4_HOS_C2_45
						C_1_C7_45	
				Electro-encep halography	C_1_C5_54	C_1_C6_54	D4_HOS_C2_54
						C_1_C7_54	
Radiology	Radiology Charges	028X, 032X, 033X, 034X, 035X and 040X		Radiology - Diagnostic	C_1_C5_41	C_1_C6_41	D4_HOS_C2_41
						C_1_C7_41	
	MRI Charges	061X		Radiology - Therapeutic	C_1_C5_42	C_1_C6_42	D4_HOS_C2_42
				Radioisotope	C_1_C5_43	C_1_C6_43	D4_HOS_C2_43
						C_1_C7_43	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4)	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number)	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number)	Medicare Charges from HCRIS (Worksheet D-4, Column & line number)
Emergency Room	Emergency Room Charges	045x		Emergency	C_1_C5_61	C_1_C6_61	D4_HOS_C2_61
						C_1_C7_61	
Blood and Blood Products	Blood Charges	038x		Whole Blood & Packed Red Blood Cells	C_1_C5_46	C_1_C6_46	D4_HOS_C2_46
						C_1_C7_46	
	Blood Storage / Processing	039x		Blood Storing, Processing, & Transfusing	C_1_C5_47	C_1_C6_47	D4_HOS_C2_47
						C_1_C7_47	
Other Services	Lithotripsy Charge	079X					
	Other Service Charge	0002-0099, 022X, 023X, 024X,052X,053X					
		055X-060X, 064X-070X, 076X-078X, 090X-095X and 099X					
				ASC (Non Distinct Part)	C_1_C5_58	C_1_C6_58	D4_HOS_C2_58
						C_1_C7_58	
	Outpatient Service Charges	049X and 050X		Other Ancillary	C_1_C5_59	C_1_C6_59	D4_HOS_C2_59
						C_1_C7_59	
				Clinic	C_1_C5_60	C_1_C6_60	D4_HOS_C2_60
						C_1_C7_60	
	Ambulance Charges	054X					

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description (Worksheet C Part 1 & Wksheet D-4)	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number)	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number)	Medicare Charges from HCRIS (Worksheet D-4, Column & line number)
	ESRD Revenue Setting Charges	080X and 082X-088X		Observation beds	C_1_C5_62	C_1_C6_62	D4_HOS_C2_62
						C_1_C7_62	
	Clinic Visit Charges	051X		Observation beds	C_1_C5_6201	C_1_C6_6201	D4_HOS_C2_6201
	(excluding Labor & Delivery DRGs)					C_1_C7_6201	
				Rural Health Clinic	C_1_C5_6350	C_1_C6_6350	D4_HOS_C2_6350
	Professional Fees Charges	096X, 097X, and 098X				C_1_C7_6350	
				FQHC	C_1_C5_6360	C_1_C6_6360	D4_HOS_C2_6360
						C_1_C7_6360	
				Home Program Dialysis	C_1_C5_64	C_1_C6_64	D4_HOS_C2_64
						C_1_C7_64	
				Ambulance	C_1_C5_65	C_1_C6_65	D4_HOS_C2_65
						C_1_C7_65	
				Other Reimbursable	C_1_C5_68	C_1_C6_68	D4_HOS_C2_68
						C_1_C7_68	

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We developed the national average CCRs as follows:

Taking the FY 2009 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland as we are including their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–4 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–4. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 15 cost centers by the corresponding national average CCR, we summed the 15 "costs" across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight.

The new cost-based relative weights were then normalized by an adjustment factor of 1.5798292955 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The 15 proposed national average CCRs for FY 2012 are as follows:

Group	CCR
Routine Days	0.514
Intensive Days	0.448
Drugs	0.199
Supplies & Equipment	0.331
Therapy Services	0.381
Laboratory	0.145
Operating Room	0.251
Cardiology	0.154
Radiology	0.140
Emergency Room	0.239
Blood and Blood Products	0.408
Other Services	0.395
Labor & Delivery	0.470
Inhalation Therapy	0.192
Anesthesia	0.117

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. In this FY 2012 IPPS/LTCH PPS proposed rule, we are proposing to use that same case threshold in recalibrating the MS–DRG weights for FY 2012. Using the FY 2010 MedPAR data set, there are 8 MS–DRGs that contain fewer than 10 cases. Under the MS–DRGs, we have fewer low-volume DRGs than under the CMS DRGs because we no longer have separate DRGs for patients age 0 to 17 years. With the exception of newborns, we previously separated some DRGs based on whether the patient was age 0 to 17 years or age 17 years and older. Other than the age split, cases grouping to these DRGs are identical. The DRGs for patients age 0 to 17 years generally have very low volumes because children are typically ineligible for Medicare. In the past, we have found that the low volume of cases for the pediatric DRGs could lead to significant year-to-year instability in their relative weights. Although we have always encouraged non-Medicare payers to develop weights applicable to their own patient populations, we have heard frequent complaints from providers about the use of the Medicare relative weights in the pediatric population. We believe that eliminating this age split in the MS–DRGs will provide more stable payment for pediatric cases by determining their payment using adult cases that are much higher in total volume. Newborns are unique and require separate MS–DRGs that are not mirrored in the adult population. Therefore, it remains necessary to retain separate MS–DRGs for newborns. All of the low-volume MS–DRGs listed below are for newborns. In FY 2012, because we do not have sufficient MedPAR data to set accurate and stable cost weights for these low-volume MS–DRGs, we are

proposing to compute weights for the low-volume MS–DRGs by adjusting their FY 2011 weights by the percentage change in the average weight of the cases in other MS–DRGs. The crosswalk table is shown below:

Low-Volume MS-DRG	MS-DRG Title	Crosswalk to MS-DRG
768	Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
789	Neonates, Died or Transferred to Another Acute Care Facility	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	FY 2011 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)

I. Proposed Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as "new technologies") under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, "based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate." We note that beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs.

The regulations implementing these provisions specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. These

three criteria are explained below in the ensuing paragraphs in further detail.

Under the first criterion, as reflected in 42 CFR 412.87(b)(2), a specific medical service or technology will be considered "new" for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. Typically, there is a lag of 2 to 3 years from the point a new medical service or technology is first introduced on the market (generally on the date that the technology receives FDA approval/clearance) and when data reflecting the use of the medical service or technology are used to calculate the MS–DRG weights. For example, data from discharges occurring during FY 2010 are used to calculate the FY 2012 MS–DRG weights in this proposed rule. Section 412.87(b)(2) of the regulations therefore provides that "a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new medical service or technology (depending on when a new code is assigned and data on the new medical service or technology become available for DRG recalibration). After CMS has recalibrated the MS–DRGs, based on available data to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion for this section."

The 2-year to 3-year period during which a medical service or technology can be considered new would ordinarily begin on the date on which the medical service or technology received FDA approval or clearance. (We note that, for purposes of this section of this proposed rule, we generally refer to both FDA approval and FDA clearance as FDA "approval.") However, in some cases, there may be few to no Medicare data available for the new service or technology following FDA approval. For example, the newness period could extend beyond the 2-year to 3-year period after FDA approval is received in cases where the product initially was generally unavailable to Medicare patients following FDA approval, such as in cases of a national noncoverage determination or a documented delay in bringing the product onto the market after that approval (for instance, component production or drug production has been postponed following FDA approval due to shelf life concerns or manufacturing issues). After the MS–DRGs have been recalibrated to reflect the costs of an otherwise new medical service or technology, the medical service or technology is no longer eligible for special add-on payment for new medical services or technologies (as specified under § 412.87(b)(2)). For example, an approved new technology that received FDA approval in October 2009 and entered the market at that time may be eligible to receive add-on payments as a new technology for discharges occurring before October 1, 2012 (the start of FY 2013). Because the FY 2013 MS–DRG weights would be calculated using FY 2011 MedPAR data, the costs of such a new technology would be fully reflected in the FY 2013 MS–DRG weights. Therefore, the new technology would no longer be eligible to receive add-on payments as a new technology for discharges occurring in FY 2013 and thereafter.

We do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval, it may not necessarily be considered "new" for purposes of new technology add-on payments if it is "substantially similar" to a technology that was approved by FDA and has been on the market for more than 2 to 3 years. In the FY 2006 IPPS final rule (70 FR 47351), we explained our policy regarding substantial similarity in detail and its relevance for assessing if the hospital charge data used in the development of the relative weights for the relevant DRGs reflect the costs of the technology. In that final rule, we stated that, for determining substantial similarity, we consider (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, and (2) whether a product is assigned to the same or a different DRG. We indicated that both of the above criteria should be met in order for a technology to be considered "substantially similar" to an existing technology. However, in that same final rule, we also noted that, due to the complexity of issues regarding the substantial similarity component of the newness criterion, it may be necessary to exercise flexibility when considering whether technologies are substantially similar to one another. Specifically, we stated that we may consider additional factors, depending on the circumstances specific to each application.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 and 43814), we noted that the discussion of substantial similarity in the FY 2006 IPPS final rule related to comparing two separate technologies made by different manufacturers. Nevertheless, we stated that the criteria discussed in the FY 2006 IPPS final rule also are relevant when comparing the similarity between a new use and existing uses of the same technology (or a very similar technology manufactured by the same manufacturer). In other words, we stated that it is necessary to establish that the new indication for which the technology has received FDA approval is not substantially similar to that of the prior indication. We explained that such a distinction is necessary to determine the appropriate start date of the newness period in evaluating whether the technology would qualify for add-on payments (that is, the date of the "new" FDA approval or that of the prior approval), or whether the technology could qualify for separate new technology add-on payments under each indication.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43814), we added a third factor of consideration to our analysis of whether a new technology is substantially similar to one or more existing technologies. Specifically, in making a determination of whether a technology is substantially similar to an existing technology, we adopted a policy to consider whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population (74 FR 24130), in addition to considering the already established factors described in the FY 2006 IPPS final rule (that is, (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; and (2) whether a product is assigned to the same or a different DRG). As we noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule, if all three components are present and the new use is deemed substantially similar to one or more of the existing uses of the technology (that is, beyond the newness period), we would conclude that the technology is not new and, therefore, is ineligible for the new technology add-on payment.

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to the discharge involving the new medical services or technologies must be assessed for adequacy. Under the cost criterion, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold

amounts. In the FY 2004 IPPS final rule (68 FR 45385), we established the threshold at the geometric mean standardized charge for all cases in the MS–DRG plus 75 percent of 1 standard deviation above the geometric mean standardized charge (based on the logarithmic values of the charges and converted back to charges) for all cases in the MS–DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs, if the new medical service or technology occurs in more than one MS–DRG).

However, section 503(b)(1) of Public Law 108–173 amended section 1886(d)(5)(K)(ii)(I) of the Act to provide that, beginning in FY 2005, CMS will apply "a threshold * * * that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved." (We refer readers to section IV.D. of the preamble to the FY 2005 IPPS final rule (69 FR 49084) for a discussion of the revision of the regulations to incorporate the change made by section 503(b)(1) of Pub. L. 108–173.) Table 10 that was included in the IPPS/LTCH PPS final rule published in the **Federal Register** on August 16, 2010, contained the final thresholds that were used to evaluate applications for new technology add-on payments for this proposed rule for FY 2012 (75 FR 50605 through 50613).

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR Parts 160 and 164 applies to claims information that providers submit with applications for new technology add-on payments. Specifically, we explained that health plans, including Medicare, and providers that conduct certain transactions electronically, including hospitals that would receive new technology add-on payments, are required to comply with the HIPAA Privacy Rule. We further explained how such entities could meet the applicable HIPAA requirements by discussing how the HIPAA Privacy Rule permitted providers to share with health plans information needed to ensure correct payment, if they had obtained consent from the patient to use that patient's data for treatment, payment, or health care operations. We also explained that, because the information to be provided within applications for new technology add-on payment would be needed to ensure correct payment, no additional consent would be required. The HHS Office for Civil Rights has since amended the HIPAA Privacy Rule, but the results remain. The HIPAA Privacy Rule does not require a covered entity to obtain consent from patients to use or disclose protected health information for the covered entity's treatment, payment, or health care operations purposes, and expressly permits such entities to use or to disclose protected health information for these purposes and for the treatment purposes of another health care provider and the payment purposes of another covered entity or health care provider. (We refer readers to 45 CFR 164.502(a)(1)(ii) and 164.506(c)(1) and (c)(3) and the Standards for Privacy of Individually Identifiable Health Information published in the **Federal Register** (67 FR 53208 through 53214) on August 14, 2002, for a full discussion of consent in the context of the HIPAA Privacy Rule.)

Under the third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents "an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available. (We refer readers to the September 7, 2001 final rule for a complete discussion of this criterion (66 FR 46902).)

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Under § 412.88, if the costs of the discharge (determined by applying cost to charge ratios ("CCRs") as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology.

Section 1886(d)(4)(C)(iii) of the Act requires that the adjustments to annual MS–DRG classifications and relative weights be made in a manner that ensures that aggregate payments to hospitals are not more or less than they were in the prior fiscal year (i.e., they are "budget neutral"). Therefore, in the past, we accounted for projected payments under the new medical service and technology provision during the upcoming fiscal year, while at the same time estimating the payment effect of changes to the MS–DRG classifications and recalibration. The impact of additional payments under this provision was then included in the budget neutrality factor, which was applied to the standardized amounts and the hospital-specific amounts. However, section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criteria, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We also amended § 412.87(c) to specify that all applicants for new technology add-on payments must have FDA approval or clearance for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

The Council on Technology and Innovation (CTI) at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies between CMS and other

entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Office of Clinical Standards and Quality (OCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, OCSQ, and the local claims-payment contractors (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

CMS plans to continue its Open Door forums with stakeholders who are interested in CTI's initiatives. In addition, to improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an "Innovator's Guide" to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS Web site, in a user-friendly format. This guide was published in August 2008 and is available on the CMS Web site at: *http://www.cms.gov/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf.*

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov.*

We note that applicants for add-on payments for new medical services or technologies for FY 2013 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp.* To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2013, the Web site also will post the tracking forms completed by each applicant.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2012 prior to publication of the FY 2012 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 29, 2010 (75 FR 73091 through 73094), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 2, 2011. In the announcement notice for the meeting, we stated that the opinions and alternatives provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for each of the FY 2012 new medical service and technology add-on payment applications before the publication of the FY 2012 proposed rule.

Approximately 50 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. Each of the three FY 2012 applicants presented information on its technology, including a discussion of data reflecting the substantial clinical improvement aspect of the technology. We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications, in our evaluation of the new technology add-on applications for FY 2012 in this proposed rule.

In response to the published notice and the new technology town hall meeting, we received three written comments regarding applications for FY 2012 new technology add-on payments. We summarize these comments or, if applicable, indicate that there were no comments received, at the end of each discussion of the individual applications in this proposed rule.

Comment: A number of attendees at the new technology town hall meeting provided comments that were unrelated to "substantial clinical improvement."

Response: As explained above and in the **Federal Register** notice announcing the meeting (75 FR 73091), the purpose of the new technology town hall meeting was specifically to discuss substantial clinical improvement of pending new technology applications for FY 2012. Therefore, we are not summarizing those comments in this proposed rule. Commenters are welcome to resubmit these comments in

response to proposals in this proposed rule.

Comment: One commenter, a major device association, requested that CMS provide more flexibility for the substantial clinical improvement criteria by allowing new technologies to demonstrate a substantial likelihood that clinical improvement will result. The commenter believed that this request was not unreasonable, given the fact that conclusive evidence would not necessarily be available in the short period of time for which an add-on payment would be available. The commenter also suggested that CMS consider a broader range of evidence in assessing whether a new technology meets the test of providing substantial clinical improvement over an older technology.

Response: As stated in the 2001 new technology add-on payment final rule (66 FR 46913), we believe that the "substantial clinical improvement" criterion is intended "to limit these special payments for those technologies that afford clear improvements over the use of previously available technologies." We believe that special payments for new technology should be limited to those new technologies that have been demonstrated to represent a substantial clinical improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. If such an improvement is not demonstrated, we continue to believe the incentives of the MS–DRG system provide a useful balance to the introduction of new technologies. In that regard, we point out that various new technologies introduced over the years have been demonstrated to have been less effective than initially thought, or in some cases even potentially harmful. We believe it is in the best interest of Medicare beneficiaries for CMS to proceed carefully with respect to the incentives created to quickly adopt new technologies.

With respect to the comment that CMS should consider a broader range of evidence in assessing whether a new technology meets the test of providing substantial clinical improvement over an older technology, we accept different types of data (for example, peer-reviewed articles, study results, or letters from major associations, among others) that demonstrate and support the substantial clinical improvement associated with the new technology. In addition to clinical data, we will consider any evidence that would support the substantial clinical improvement associated with a new technology. Therefore, we believe we already consider an appropriate range of evidence as the commenter has requested.

Comment: One commenter stated that, while it appreciated that new technology add-on payments are intended to encourage innovation, CMS' application of the substantial clinical improvement criterion fails to account for how many technological advances may occur in practice. The commenter expressed confidence that many recent design improvements in medical devices represent significant advances in clinical utility of older/established technologies, and indicated CMS may fail to recognize these improvements in the current context of applying add-on payments.

Response: As discussed above, a service or technology is not "new" for purposes of the new technology add-on payment if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval, it may not necessarily be considered "new" for purposes of new technology add-on payments if it is "substantially similar" to a technology that was approved by FDA and has been on the market for more than 2 to 3 years. To determine substantial similarity, we consider (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, (2) whether a product is assigned to the same or a different DRG and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. As we noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), if all three components are present and the new use is deemed substantially similar to one or more of the existing uses of the technology (that is, beyond the newness period), we would conclude that the technology is not new and, therefore, is ineligible for the new technology add-on payment. A complete discussion of the substantial similarity criteria and policy can be found in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814)

Comment: One commenter believed that CMS has narrowly interpreted the statutory criteria for granting new technology add-on payments, which has created a situation in which it has become increasingly difficult for new technologies to qualify for this add-on payment. The commenter asserted that the criteria are so steep and the process so opaque that many companies, especially small companies, cannot afford to undertake the process at all. The commenter recommended that CMS continue to engage stakeholders to improve the new technology add-on payment process. The commenter also recommended that CMS consider creating additional guidance to further clarify the requirements as to what qualifies as a new technology. The commenter believed that additional guidance could provide greater certainty and predictability for many companies developing novel technologies.

Response: We believe it is important to maintain an open dialogue on the IPPS new technology add-on payment process, as well as the broader issue of how new technology is introduced into all of the Medicare payment systems. As announced in a notice published in the **Federal Register** (75 FR 73091 through 73094), on February 2, 2011, prior to the new technology town hall meeting, we held an informational workshop for the general public that gave an overview on the processes of the new technology provisions in both the inpatient hospital and outpatient hospital settings, in addition to the procedures involved with ICD–9–CM coding and MS–DRG reassignment under the IPPS. We believe that our annual new technology town hall meeting and rulemaking process (including the posting of the applicants' tracking forms on the CMS Web site) allow for an ongoing dialogue between CMS and the public on the new technology add-on payment process. Furthermore, we are willing to meet with potential applicants prior to and after an application has been submitted in order to ensure an application meets the submission requirements and to provide technical feedback on an applicant's application.

In reference to the commenter's general statement that CMS' interpretation of the statutory criteria has been narrowly cited, we are interested in and welcome comment on any specific criteria or data quality standards that commenters believe we should adopt to improve the new technology add-on application process, or any concerns or challenges that commenters believe we may encounter in undertaking this effort. Again, as we stated at the new technology town hall meeting, we are interested in working with stakeholders to improve the inpatient new technology add-on payment process. We are interested in ensuring that the latest medical technology that improves care for the Medicare patient population continues to be available to our beneficiaries. In addition, we invite potential applicants to contact CMS with any specific questions or concerns they may have prior to the submission of their

application for new technology add-on payment.

3. FY 2012 Status of Technologies Approved for FY 2011 Add-On Payments

a. Spiration® IBV® Valve System

Spiration, Inc. submitted an application for new technology add-on payments for the Spiration® IBV® Valve System (Spiration® IBV®). The Spiration® IBV® is a device that is used to place, via bronchoscopy, small, one-way valves into selected small airways in the lung in order to limit airflow into selected portions of lung tissue that have prolonged air leaks following surgery while still allowing mucus, fluids, and air to exit, thereby reducing the amount of air that enters the pleural space. The device is intended to control prolonged air leaks following three specific surgical procedures: Lobectomy; segmentectomy; or lung volume reduction surgery (LVRS). According to the applicant, an air leak that is present on postoperative day 7 is considered "prolonged" unless present only during forced exhalation or cough. In order to help prevent valve migration, there are five anchors with tips that secure the valve to the airway. The implanted valves are intended to be removed no later than 6 weeks after implantation.

With regard to the newness criterion, the Spiration® IBV® received a HDE approval from the FDA on October 24, 2008. We were unaware of any previously FDA-approved predicate devices, or otherwise similar devices, that could be considered substantially similar to the Spiration® IBV®. However, the applicant asserted that the FDA had precluded the device from being used in the treatment of any patients until the Institutional Review Board (IRB) granted approvals regarding its study sites. Therefore, the Spiration® IBV® met the newness criterion once it obtained at least one IRB approval because the device would then be available on the market to treat Medicare beneficiaries. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43819), the applicant stated that the first IRB approval for the Spiration® IBV® was March 12, 2009. In that final rule, based on the information above from the applicant, we determined that the Spiration® IBV® meets the newness criterion and the newness period for the Spiration® IBV® begins on March 12, 2009.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the Spiration® IBV® and consideration of the public comments we received in response to the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, including the additional analysis of clinical data and supporting information submitted by the applicant, we approved the Spiration® IBV® for new technology add-on payments for FY 2010 with a maximum add-on payment of $3,437.50.

In the FY 2011 IPPS/LTCH PPS proposed rule, we did not propose any changes to the new technology add-on payments for the Spiration® IBV®. We did not receive any public comments on whether to continue or discontinue the new technology add-on payment for the Spiration® IBV® for FY 2011. Therefore, for FY 2011, we continued new technology add-on payments for cases involving the Spiration® IBV® in FY 2011, with a maximum add-on payment of $3,437.50.

The new technology add-on payment regulations provide that "a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new medical service or technology" (42 CFR 412.87(b)(2)). Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend add-on payments for an additional year only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362). With regard to the newness criterion for the Spiration® IBV®, as stated above, we consider the beginning of the newness period for the device to have commenced on the date of the first IRB approval for the Spiration® IBV®, which was March 12, 2009. For FY 2012, as of March 12, 2012, the Spiration® IBV® will have been on the market for 3 years, and is therefore no longer considered "new" as of March 12, 2012. Because the 3-year anniversary date of the Spiration® IBV®'s entry onto the market will occur in the first half of the fiscal year, we are proposing to discontinue its new technology add-on payment for FY 2012.

b. CardioWest™ Temporary Total Artificial Heart System (CardioWest™ TAH-t)

SynCardia Systems, Inc. submitted an application for approval of the CardioWest™ Temporary Total Artificial Heart System (TAH-t) in FY 2009. The TAH-t is a technology that is used as a bridge to heart transplant device for heart transplant-eligible patients with end-stage biventricular failure. The TAH-t pumps up to 9.5 liters of blood per minute. This high level of perfusion helps improve hemodynamic function in patients, thus making them better heart transplant candidates.

The TAH-t was approved by the FDA on October 15, 2004, for use as a bridge to transplant device in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. The TAH-t is intended to be used in hospital inpatients. One of the FDA's post-approval requirements is that the manufacturer agrees to provide a post-approval study demonstrating that success of the device at one center can be reproduced at other centers. The study was to include at least 50 patients who would be followed up to 1 year, including (but not limited to) the following endpoints: Survival to transplant; adverse events; and device malfunction.

In the past, Medicare did not cover artificial heart devices, including the TAH-t. However, on May 1, 2008, CMS issued a final national coverage determination (NCD) expanding Medicare coverage of artificial hearts when they are implanted as part of a study that is approved by the FDA and is determined by CMS to meet CMS' Coverage with Evidence Development (CED) clinical research criteria. (The final NCD is available on the CMS Web site at: *http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=211*.)

We indicated in the FY 2009 IPPS final rule (73 FR 48555) that, because Medicare's previous coverage policy with respect to this device had precluded payment from Medicare, we did not expect the costs associated with this technology to be currently reflected in the data used to determine the relative weights of MS–DRGs. As we have indicated in the past, and as we discussed in the FY 2009 IPPS final rule, although we generally believe that the newness period would begin on the date that FDA approval was granted, in cases where the applicant can demonstrate a documented delay in market availability subsequent to FDA approval, we would consider delaying the start of the newness period. This technology's situation represented such a case. We also noted that section 1886(d)(5)(K)(ii)(II) of the Act requires that we provide for the collection of cost data for a new medical service or technology for a period of at least 2 years and no more than 3 years "beginning on the date on which an inpatient hospital code is issued with

respect to the service or technology." Furthermore, the statute specifies that the term "inpatient hospital code" means any code that is used with respect to inpatient hospital services for which payment may be made under the IPPS and includes ICD–9–CM codes and any subsequent revisions. Although the TAH-t has been described by the ICD–9–CM code(s) since the time of its FDA approval, because the TAH-t had not been covered under the Medicare program (and, therefore, no Medicare payment had been made for this technology), this code could not be "used with respect to inpatient hospital services for which payment" is made under the IPPS, and thus we assumed that none of the costs associated with this technology would be reflected in the Medicare claims data used to recalibrate the MS–DRG relative weights for FY 2009. For this reason, as discussed in the FY 2009 IPPS final rule, despite the FDA approval date of the technology, we determined that TAH-t would still be eligible to be considered "new" for purposes of the new technology add-on payment because the TAH-t met the newness criterion on the date that Medicare coverage began, consistent with issuance of the final NCD, effective on May 1, 2008.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the TAH-t and consideration of the public comments we received in response to the FY 2009 IPPS proposed rule, we approved the TAH-t for new technology add-on payments for FY 2009 (73 FR 48557). We also continued to make new technology add-on payments for the TAH-t in FY 2010 and FY 2011.

We describe the new technology add-on payment requirements with regard to newness above. With regard to the newness criterion for the TAH-t, as stated above, we consider the beginning of the newness period for the device to have commenced from the Medicare NCD date of May 1, 2008; it is no longer considered new as of May 11, 2011. Because the 3-year anniversary date of the TAH-t will occur prior to the start of FY 2012, we are proposing to discontinue the new technology add-on payment for the TAH-t in FY 2012.

c. Auto Laser Interstitial Thermal Therapy (AutoLITT™) System

Monteris Medical submitted an application for new technology add-on payments for FY 2011 for the AutoLITT™. AutoLITT™ is a minimally invasive, MRI-guided laser tipped catheter designed to destroy malignant brain tumors with interstitial thermal energy causing immediate coagulation and necrosis of diseased tissue. The technology can be identified by ICD–9–CM procedure codes 17.61 (Laser interstitial thermal therapy [LITT] of lesion or tissue of brain under guidance), and 17.62 (Laser interstitial thermal therapy [LITT] of lesion or tissue of head and neck under guidance), which became effective on October 1, 2009.

The AutoLITT™ received a 510K FDA clearance in May 2009. The AutoLITT™ is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers. The AutoLITT™ may be used in patients with glioblastoma multiforme brain (GBM) tumors. The applicant stated in its application and through supplemental information that, due to required updates, the technology was actually introduced to the market in December 2009. The applicant explained that it was necessary to reduce the thermal damage lines from three to one and complete International Electrotechnical Commission/ Underwriter Laboratory testing, which led to the introduction of the technology to the market in December 2009, although the technology was approved by FDA in May 2009. The applicant also stated through supplementary information to its application that the first sale of the product took place on March 19, 2010. However, because the product was already available for use in December 2009, it appears that the newness date would begin in December 2009. In the FY 2011 IPPS/LTCH PPS proposed rule, we welcomed public comments on this issue.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the AutoLITT™ and consideration of the public comments we received in response to the FY 2011 IPPS/RY 2011 LTCH PPS proposed rule, including the additional analysis of clinical data and supporting information submitted by the applicant, we approved the AutoLITT™ for new technology add-on payments for FY 2011. Consistent with the applicant's clinical trial, the add-on payment is intended only for use of the device in cases of Glioblastoma Multiforme. Therefore, we limited the new technology add-on payment to cases involving the AutoLITT™ in MS–DRGs 025 (Craniotomy and Endovascular Intracranial Procedures with MCC), 026 (Craniotomy and Endovascular Intracranial Procedures with CC), and 027 (Craniotomy and Endovascular Intracranial Procedures without CC or MCC). Cases involving the AutoLITT™ that are eligible for the new technology add-on payment are identified by assignment to MS–DRGs 025, 026, and 027 with a procedure code of 17.61 (Laser interstitial thermotherapy of lesion or tissue of brain under guidance) in combination with a primary diagnosis code that begins with a prefix of 191 (Malignant neoplasm of brain). We note that using the procedure and diagnosis codes above and restricting the add-on payment to cases that map to MS–DRGs 025, 026, and 027 is consistent with information provided by the applicant, which demonstrated that cases of the AutoLITT™ would only map to MS–DRGs 025, 026, and 027. Procedure code 17.62 (Laser interstitial thermotherapy of lesion or tissue of head and neck under guidance) does not map to MS–DRGs 025, 026, or 027 under the GROUPER software and, therefore, is ineligible for new technology add-on payment.

The average cost of the AutoLITT™ is reported as $10,600 per case. Under § 412.88(a)(2) of the regulations, new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case involving the AutoLITT™ is $5,300.

We describe the new technology add-on payment requirements with regard to newness above. With regard to the newness criterion for the AutoLITT™, as stated above, we consider the beginning of the newness period for the device to commence from the market release date of December 2009. Therefore, the device will be considered "new" until December 2012. Because the 3-year anniversary date for the AutoLITT™ will occur after FY 2012, we are proposing to continue to make new technology add-on payments for the AutoLITT™ in FY 2012.

4. FY 2012 Applications for New Technology Add-On Payments

a. AxiaLIF® 2L+™ System

TranS1 submitted an application for new technology add-on payments for the AxiaLIF® 2L+™ System for FY 2012. The AxiaLIF® 2L+™ System is an implantable spinal fixation system, delivered through a pre-sacral approach, facilitating spinal fusion through axial stabilization of the anterior lumbar spine at Lumbar vertebrae 4 through Sacral vertebrae 1 (L4–S1).

The AxiaLIF® 2L+™ System received 510K FDA clearance (K092124) on January 21, 2010, and the applicant asserts that the device was available on the market immediately afterward through a limited market release program. The AxiaLIF® 2L+™ System is indicated for use to provide anterior stabilization of the L4–S1 spinal segments as an adjunct to spinal fusion. It is also indicated for minimally invasive access to the anterior portion of the lower spine for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy, or for assistance in the performance of L4–S1 interbody fusion. The AxiaLIF® 2L+™ System may be used in patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AxiaLIF® 2L+™ System is coded using ICD–9–CM procedure code 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique).

With regard to the newness criterion, we are concerned that the AxiaLIF® 2L+™ System may be substantially similar to the other devices manufactured by the applicant, AxiaLIF® System and AxiaLIF® II™ System, the latter of which is listed as the predicate device on the AxiaLIF® 2L+™ System's application for FDA approval. Specifically, in making a determination of substantial similarity, we consider the following: (1) Whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or different DRG; and (3) whether the new use of a technology involves the treatment of the same or similar type of disease and the same or similar patient population.

We are particularly concerned that the AxiaLIF® 2L+™ System uses the same or similar mechanism of action as the AxiaLIF® II™ System to achieve a therapeutic outcome. According to the applicant's 510K summary submitted to the FDA (K073514), the AxiaLIF® System is a multicomponent system including titanium alloy implantable devices and instrumentation for creating a pre-sacral axial track to the L5–S1 disk space. Similarly, the AxiaLIF® II™ System is described in the applicant's 510K summary submitted to the FDA (K073643) as a system of medical grade titanium alloy for the anterior stabilization of the L4–S1 spinal segments as an adjunct to spinal fusion. The applicant states that the AxiaLIF® 2L+™ System was created from the AxiaLIF® II™ System platform. The applicant submitted the following to distinguish the AxiaLIF® 2L+™ System from the AxiaLIF® II™ System:

- There have been internal thread changes for the 2L+ implant to accompany the Spanning Distraction Rod, which is designed to create and hold distraction in the L5–S1 disc space and allow for a higher degree of control over the Rod advancement and distraction;
- The design enhancements in the 2L+ System remove the dependence of distraction on size and placement of the S1 Rod, thus allowing precise implant placement in the vertebral bodies;
- In the 2L+ Implant, the L4 section of the L4–L5 Rod incorporates a conical design to increase fixation. The outer diameter (O.D.) of the L5 section is increased to be identical to the O.D. of the S1 implant to provide more surface area bone contact;
- The 2L+ Instrumentation incorporates Dilator Trials as an opportunity to enhance and simplify the intraoperative measuring technique by providing a direct visual means of measurement; and
- The 2L+ Fixation Rod fills the cannulation to prevent graft from moving into the rod from the disc space. The Fixation Rod also fixates the S1 Anchor and L4–L5 Rod together such that these components cannot passively separate.

Based on indications for use listed by the FDA for the AxiaLIF® System (K073514), the AxiaLIF® II™ System (K073643), and the AxiaLIF® 2L+™ System (as described above), we also are concerned that all of these devices involve the treatment of the same or similar type of disease and the same or similar patient population. With respect to whether a product is assigned to the same or different DRG, we note that currently the AxiaLIF® System and the AxiaLIF® 2L+™ System both generally map to MS–DRGs 459 (Spinal Fusion Except Cervical with MCC) and 460 (Spinal Fusion Except Cervical without MCC). Though the AxiaLIF® II™ System is no longer on the market, it would also map to the same DRGs.

If the AxiaLIF® 2L+™ System is found to be substantially similar to the AxiaLIF® System or the AxiaLIF® II™ System, the AxiaLIF® 2L+™ System would no longer qualify for the new technology add-on payment. Specifically, the appropriate start date for the AxiaLIF® 2L+™ System would be the start date of the device that is found to be substantially similar to the AxiaLIF® 2L+™ System. As noted above, the AxiaLIF® II™ System received FDA approval on April 28, 2008. The 3-year newness period for the AxiaLIF® II™ System ends prior to the start of FY 2012 (July 28, 2011). Given the length of time since the AxiaLIF® II™ System's entry into the market, cost-related data for the AxiaLIF® II™ System is already reflected in the most recent MS–DRG relative weights. Additionally, the AxiaLIF® System received multiple FDA approvals, the most recent of which was on January 11, 2008. The 3-year newness period for the AxiaLIF® System also ends prior to the start of FY 2012 (January 11, 2011). Given the length of time since the AxiaLIF® System's entry into the market, cost-related data for the AxiaLIF® System is already reflected in the most recent MS–DRG relative weights. However, if the AxiaLIF® 2L+™ System is not substantially similar to any of the predicate devices mentioned above, then the newness period for the AxiaLIF® 2L+™ System would begin on January 21, 2010 (the AxiaLIF® 2L+™ System's FDA approval date) and would be within the year newness period for FY 2012. We invite public comment regarding whether or not the AxiaLIF® 2L+™ System meets the newness criteria, and, in particular, whether it is substantially similar to the AxiaLIF® System or the AxiaLIF® II™ System.

In an effort to demonstrate that the AxiaLIF® 2L+™ System meets the cost criterion, the applicant used data from the FY 2009 MedPAR file. The applicant explained through supplemental information to its application that most cases of the AxiaLIF® 2L+™ System would map to MS–DRGs 459 (Spinal Fusion Except Cervical with MCC) and 460 (Spinal Fusion Except Cervical without MCC). The applicant searched the FY 2009 MedPAR file for cases with an ICD–9–CM procedure code of 81.08 (Lumbar and lumbosacral fusion of the anterior column, posterior technique). The applicant found 2,533 cases in MS–DRG 459 (5 percent of all cases) and 48,135 cases in MS–DRG 460 (95 percent of all cases). The average standardized charge per case was $117,847 for MS–DRG 459 and $84,153 for MS–DRG 460, equating to a case-weighted average standardized charge per case of $77,195.

This case-weighted standardized charge per case contains charges related to other implantable devices. Therefore, it is necessary to remove charges of other implantable devices from the case-weighted standardized charge per case (before substituting charges for the AxiaLIF® 2L+™ System). The applicant used the following methodology to

determine the average amount of charges related to other implantable devices within the case-weighted average standardized charge per case. The applicant estimated a standardized medical/surgical supplies charge of $47,860. After searching all claims in the CY 2008 100 percent inpatient limited data set standardized file, the applicant determined that, on average, implantable devices (revenue center 0278) accounted for 75 percent of the of medical/surgical supplies charges, equating to $36,104 for the cases the applicant found in MS–DRGs 459 and 460. The applicant then subtracted this amount from the case-weighted average standardized charge per case, which resulted in a case-weighted average standardized charge per case, excluding an implantable device, of $41,090 ($77,195 − $36,104).

The applicant then estimated the charges for the AxiaLIF® 2L+™ System by inflating the expected purchase price of the AxiaLIF® 2L+™ System by 2.77 times the purchase price of defibrillators, resulting in a standardized charge of $51,482 for the AxiaLIF® 2L+™ System. The applicant stated that using a markup based on defibrillators was appropriate because, like the AxiaLIF® 2L+™ System, defibrillators are also a high-cost implantable device. The applicant then added the average standardized charge for the AxiaLIF® 2L+™ System to the average standardized charge per case excluding an implantable device, which resulted in a total case-weighted average standardized charge per case of $92,557 ($41,075 + $51,482). The applicant calculated a case-weighted threshold of $78,354 for MS–DRGs 459 and 460. Because the total average standardized charge per case ($92,557), as calculated by the applicant, exceeds the case-weighted threshold ($78,354), the applicant maintains that it meets the cost criteria.

We have concerns with the applicant's methodology. Specifically, in determining the projected standardized charge for the AxiaLIF® 2L+™ System, the applicant relies on a charge markup for defibrillators because it is also a high-cost implantable device for which a hospital purchase price is known. We are concerned about whether more direct data or different proxies are available, including a charge markup for the AxiaLIF® System or AxiaLIF® II™ System. In reviewing the applicant's charge markup, we also are concerned about the source data for determining the 2.77 charge markup ratio for defibrillators. We invite public comment on whether the AxiaLIF® 2L+™ System meets the cost criterion for a new technology add-on payment for FY 2012.

With respect to the substantial clinical improvement criterion, the applicant asserts that it meets this criterion in its application. The applicant stated that substantial clinical improvement is demonstrated by the AxiaLIF® 2L+™ System's facilitation of spinal fusion surgery without a laparotomy. By avoiding a laparotomy, the AxiaLIF® 2L+™ System reduces blood loss, postoperative pain, narcotic use, denervation, morbidity, the probability of complications, and the risk of trauma to the tissue area surrounding the lumbar. The applicant further stated that the AxiaLIF® 2L+™ System reduces morbidity and has reduced risk of injuring vital organs and important intrinsic stabilizing structures, with a lower complication profile than traditional open fusion techniques. The applicant noted that long-term results can include better support of lordosis and prevention of adjacent level disease. We are concerned that this does not demonstrate a substantial clinical improvement from the AxiaLIF® II™ System, which also facilitated spinal fusion surgery without a laparotomy.

The applicant has not conducted clinical trials, but the 300 cases of AxiaLIF® 2L+™ System's use (through the Limited Market Release) yielded a complication rate of 0.7 percent. The applicant also asserts that the pre-sacral approach results in a lower average length of stay than a non-sacral approach.

The applicant has referred us to several sources of literature presenting data related to the pre-sacral approach for the applicant's AxiaLIF® device. We are concerned that the applicant has generally repeated the statements made regarding the clinical improvement of its AxiaLIF® device and has not provided information that indicates that the AxiaLIF® 2L+™ System offers a substantial clinical benefit over the earlier AxiaLIF® or AxiaLIF® II™ devices. Moreover, the applicant has not provided any clinical outcomes data for the AxiaLIF® 2L+™ System to substantiate its assertions regarding substantial clinical improvement for the AxiaLIF® 2L+™ System. While the applicant maintains that data from the AxiaLIF® device are relevant and can be used to substantiate its assertions for the AxiaLIF® 2L+™ System, we are concerned that data directly associated with the use of the AxialLIF® 2L+™ System are not available. For example, it is not clear the degree to which the population that requires treatment with the AxiaLIF® 2L+™ System differs from the population that requires treatment with the AxiaLIF® device or the AxiaLIF® II™ System, and it is also not clear the degree to which the differences between the devices discussed above may affect clinical outcomes.

The applicant also believes that an inline placement of the fixation implant may provide an advantage due to closeness of the implant to functional axis of the spine and through alignment with the direction of the compressive forces on the vertebral bodies. The applicant maintains that evaluation and testing have proven the AxiaLIF® 2L+™ System to be a biomechanically sturdy L4–S1 axial construct that significantly reduces the range of motion at the desired point and achieves decompression by increasing the L4–S1 disc spaces. We note that the only clinical change from the AxiaLIF® device and the AxiaLIF® 2L+™ System is that the latter reaches the L4. There is no stated clinical change between the AxiaLIF® II™ and the AxiaLIF® 2L+™ System. We invite public comment on whether the AxiaLIF® 2L+™ System meets the substantial clinical improvement criterion for the new technology add-on payment for FY 2012.

b. Champion™ HF Monitoring System

CardioMEMS, Inc. submitted an application for new technology add-on payment for FY 2012 for the Champion™ HF Monitoring System, an Implantable Hemodynamic Monitor System (IHMS). The IHMS is comprised of an implantable sensor/monitor placed in the distal pulmonary artery. Pulmonary artery hemodynamic monitoring is used in the management of heart failure. The IHMS measures multiple pulmonary artery pressure parameters for an ambulatory patient to measure and transmit data via a wireless sensor to a secure Web site. The IHMS utilizes radiofrequency energy to power the sensor and to measure pulmonary artery pressure. The data are accessed by clinicians via the Internet. Interpretation of trend data allows the clinician to make adjustments to therapy while the patient is at home. Changes in pulmonary artery pressure can be used along with heart failure signs and symptoms to adjust medications. There are currently no FDA approved devices performing this IHMS function. The IHMS consists of three components: (1) A wireless implantable hemodynamic sensor/monitor which is implanted in the distal pulmonary artery (sensor); (2) an external patient measurement system; and (3) a patient data management system.

CardioMEMS, Inc. believes that a large majority of patients receiving the sensor will be admitted to an inpatient hospital with a diagnosis of "acute or chronic heart failure" (ICD–9–CM code 428.43 (Acute or chronic combine systolic and diastolic heart failure)) and the sensor will be implanted during this hospital stay. For safety considerations, a small portion of these patients may be discharged and the sensor implanted at a future date in the hospital outpatient setting. In addition, there will likely be a group of patients in chronic heart failure who are not currently hospitalized, but who have been hospitalized in the past few months for whom the treating physician believes that regular pulmonary artery pressure readings are necessary to optimize patient management. Depending on the patient's status, these patients may have the sensor implanted in the hospital inpatient or outpatient setting.

With respect to the newness criterion, we note that this device is not currently approved by the FDA, but the manufacturer anticipates that FDA approval will be granted in the second quarter of 2011. No ICD–9–CM procedure code exists at this time that uniquely identifies the System. As noted in Table 6B, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, we have approved the use of new procedure code 38.26 (Insertion of implantable wireless pressure sensor for intracardiac or great vessel hemodynamic monitoring), which will identify use of the System. The new ICD–9–CM procedure code 38.26 will be assigned to MS–DRG 264 (Other Circulatory System O.R. Procedures).

In an effort to demonstrate that the System meets the cost criteria, the applicant used data from a clinical trial. Specifically, the manufacturer used data from the *C*ardioMEMS *H*eart Sensor *A*llows Monitoring of *P*ressure to *I*mprove Outcomes in NYHA Class III heart failure patients (CHAMPION) trial [4] which enrolled 550 patients in 30 hospitals within the United States. We note that there were 575 patients initially enrolled in the trial. Of these 575 patients, 25 underwent a right heart catheterization and did not receive an implant primarily because of anatomical/physiological conditions identified during the catheterization. The manufacturer collected 310 hospital claims from the 550 patients enrolled in the CHAMPION trial. The applicant eliminated claims with incomplete data or statistical outliers, and was left with 137 claims for its cost analysis. CardioMEMS funded the clinical trial and, therefore, did not submit these 137 claims. The applicant believes that cases eligible for the System would map to MS–DRG 264. Using the 137 claims from the CHAMPION trial, the manufacturer determined an average standardized charge per case without the new technology to equal $12,817. The applicant indicated that the case-weighted average standardized charge per case does not include charges related to the System, so it is then necessary to add the charges related to the device to the average standardized charge per case to evaluate the cost threshold criterion. To convert the costs of the technology to charges, CardioMEMS used an average cost-to-charge ratio (CCR) of 0.311 based on FY 2008 hospital cost reports from the 30 hospitals who participated in the CHAMPION trial. Based on this CCR, the manufacturer determined an average charge for the System to equal $45,016. Using this methodology, the total average standardized charge per case including the new technology equals $57,833 ($45,016 + $12,817). This amount exceeds the cost threshold of $46,546 for MS–DRG 264 (Table 10 of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50607)). Because the total average standardized charge per case ($57,833) exceeds the threshold ($46,546), the applicant maintains that it meets the cost criteria.

In addition to the methodology described above, the manufacturer searched for claims for patients in the CHAMPION trial that were aged 65 years or older at the time of device implantation as a proxy for Medicare patients. Out of the original 137 hospital claims, 56 (41 percent) were for patients aged 65 years or older. From these 56 claims (across 23 hospitals from the CHAMPION study), the applicant calculated an average standardized charge of $13,031, which did not include charges for the device. The applicant added the charges related to the device ($45,016, calculated as described above) to the average standardized charge per case to evaluate the cost threshold criterion. Using this methodology, the total average standardized charge per case including the new technology equals $58,047 ($45,016 + $13,031). This amount also exceeds the FY 2012 cost threshold of $46,546 for MS–DRG 264. Because the total average standardized charge per case ($58,047) exceeds the threshold ($46,546), the applicant maintains that it meets the cost criteria. We invite public comment on whether or not the Champion™ HF Monitoring System meets the cost criterion.

With regard to substantial clinical improvement, the applicant cited clinical data from the CHAMPION trial. The trial is a prospective, multicenter, randomized, single-blinded clinical trial conducted in the United States, designed to evaluate the safety and efficacy of the System in reducing heart failure-related hospitalizations in a subset of subjects suffering from heart failure. The applicant shared several major findings from the CHAMPION trial [5] as described below. First, at 6 months, the treatment group exhibited a 30 percent relative risk reduction in the rate of heart failure-related hospitalization (0.31 vs. 0.44, $p < 0.0001$). There were 83 heart failure-related hospitalizations in 270 treatment patients compared to 120 heart failure-related hospitalizations in the 280 control subjects. The "number needed to treat" (NNT) to reduce one heart failure-related hospitalization was eight patients. Second, during the 6-month follow-up period, the proportion of subjects hospitalized for one or more heart failure-related hospitalizations was significantly lower in the treatment group (54 out of 270 patients) than in the control group (80 out of 280 patients) (20 percent vs. 28.6 percent; $p = 0.0222$). Third, at 6 months, treatment patients had more days alive outside of the hospital (174.4 vs. 172.1, $p = 0.0222$) and fewer average days in the hospital (2.2 vs. 3.8, $p = 0.0194$) compared to control patients. Treatment patients spent 472 fewer days in the hospital than the control patients. Finally, the treatment group was assessed with the Minnesota Living with Heart Failure Questionnaire, which reported a greater improvement in quality of life (QOL) than the control group (-10.6 vs. -7.4, $p = 0.0373$). The applicant concluded that the CHAMPION trial demonstrated that, with knowledge of class III heart failure patients' pulmonary artery pressures, physicians could improve medical management leading to fewer heart failure-related hospitalizations. The applicant further stated that the device

[4] *Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial.* Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, Strickland W, Neelagaru S, Raval N, Krueger S, Weiner S, Shavelle D, Jeffries B, Yadav JS; for the CHAMPION Trial Study Group. Lancet. 2011 Feb 19;377(9766):658–666.

[5] *Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial.* Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, Strickland W, Neelagaru S, Raval N, Krueger S, Weiner S, Shavelle D, Jeffries B, Yadav JS; for the CHAMPION Trial Study Group. Lancet. 2011 Feb 19;377(9766):658–666

had very few device-related and system-related complications over the course of the clinical trial, and that primary and secondary study endpoints were successfully achieved. There was one report of an "Unanticipated Serious Adverse Device Event" involving a "tingling sensation" in a control patient, which was adjudicated by the Clinical Events Committee as not device/system-related. There were two reports of Serious Adverse Device Events due to hemoptysis and a blood clot, both of which resolved without permanent sequelae. The Clinical Events Committee adjudicated both events as device/system-related. The applicant maintained that during the first 6 months, there were 336 Serious Adverse Events (hospitalizations or deaths due to heart failure or other common comorbidities seen in this population) in 121 patients in the treatment group (44.8 percent) versus 385 Serious Adverse Events in 155 patients in the control group (55.4 percent).

In addition, the manufacturer stated that the CHAMPION trial suggests the safety and effectiveness of the device was maintained during longer term follow-up. (The primary efficacy endpoint of the CHAMPION trial was 6 months. However, patients remained in their assigned groups until the last patient reached 6 months, which is referred to as "the entire follow-up." The mean time of this entire follow up was up to 15 months.) Therefore, the manufacturer believes that the System meets the substantial clinical improvement criterion. We invite public comment on whether or not the Champion™ HF Monitoring System technology represents a substantial clinical improvement in the Medicare population.

c. PerfectCLEAN With Micrillon®

UMF Corporation (the manufacturer) submitted an application for a technology called the PerfectCLEAN with Micrillon® (PerfectCLEAN). PerfectCLEAN is a cleaning textile product (or cleaning mat/wipe) with chlorine embedded or bound to the extruded fiber. The manufacturer asserts that PerfectCLEAN is intended to be used to trap and eliminate pathogens such as Methicillin-resistant Staphylococcus aureus (MRSA), Clostridium difficile (C diff.) and the H1N1 flu virus from surfaces within the hospital (as well as other health care facilities and locations). The applicant asserts that it can trap and remove more than 99.99 percent of bacteria on hard surfaces.

The manufacturer stated that the PerfectCLEAN is an Environmental Protection Agency (EPA) approved antimicrobial/disinfectant that will be available on the market in the first quarter of 2011. The applicant maintains that PerfectCLEAN is subject to review and approval by the EPA per the EPA's Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) Treated Article Exemption and, therefore, is not subject to review by the FDA. The applicant states that it was determined in a pre-registry meeting with the EPA that the underlying chemistries used to create the chlorine binding effects of Micrillon® chemistry are EPA and FDA approved even though no FDA claims are being sought.

With respect to whether the PerfectCLEAN is eligible for new technology add-on payments, we note that our regulations at § 412.87(c) state, "CMS will only consider, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA approval or clearance by July 1 prior to the particular fiscal year." FDA "approval," refers to the premarket approval application (PMA) process for most Class III devices, and FDA "clearance" refers to the 510(k) premarket notification submission process for most Class II devices and some Class I and Class III devices (section 515 of the Food, Drug and Cosmetic Act (FDCA) for PMA) and sections 510(k) and 513(i) of the FDCA (for premarket notification submission process)). Therefore, we believe our regulations, by requiring applicants to receive an FDA approval or clearance in order to be eligible for new technology add-on payments, limit the universe of items and services eligible to receive these payments to those that require FDA approval or clearance. The applicant has informed CMS that it is in the process of registering and listing its product with the FDA under section 510(b) through (d) and (j) and anticipates this process to be completed prior to the July 1 regulatory deadline. The registration process that the applicant is currently pursing will result in neither FDA approval nor clearance, and we are therefore concerned that the PerfectCLEAN is not eligible for new technology add-on payments under our existing regulations., which require "FDA approval or clearance by July 1 prior to the particular fiscal year" (42 CFR § 412.87(c)). We welcome public comments on whether the PerfectCLEAN is eligible for new technology add-on payments under the current regulations.

With regard to the cost criterion, the applicant used data from the FY 2011 After Outliers Removed (AOR) file (posted on the CMS Web site) for its cost analysis, which is based on the FY 2009 MedPAR file. The applicant considered MS–DRGs that relate to surgeries, skin abrasions, open sores, wounds, and similar inflamed tissue conditions where infection sites are thought to be more likely to occur for inpatient care situations. This resulted in the applicant determining that the technology would be most frequently used in 622 different MS–DRGs. The applicant noted that the charges from the FY 2011 AOR file were not inflated from FY 2009 to FY 2011; therefore the applicant applied a 2-year inflation factor of 12 percent (to update the charges from FY 2009 to FY 2011). The applicant based the 2-year inflation factor of 12 percent on a 3-year average of the 2 year rate-of-change in charges (the 2-year rate-of-change for FY 2009 of 11.841 percent (73 FR 48764); the 2-year rate-of-change for FY 2010 of 14.184 percent (74 FR 44010); and the 2-year rate-of-change for FY 2011 of 9.8843 percent (75 FR 50429)) that CMS uses in its outlier threshold calculation as published in section II. of the Addendum to the annual IPPS final rule. The applicant computed a case-weighted standardized charge per case of $40,442 for all 622 MS–DRGs, which did not include any charges related to the PerfectCLEAN. Therefore, it added the charges related to the technology to the case-weighted average standardized charge per case in evaluating the cost threshold criterion. The manufacturer estimates a charge per patient of $100 per day for the PerfectCLEAN. The applicant includes in this amount charges for payroll, treated textiles, packaging and protective gloves, laundering, storage, and distribution. The applicant multiplied the average length of stay for each MS–DRG (as found in Table 5 of the Addendum to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50547 through 50566)) by the charge per patient per day to determine the total charges per stay by MS–DRG related to the PerfectCLEAN. The applicant added additional charges per stay for the PerfectCLEAN to the case-weighted standardized charge per case and determined a total case-weighted average standardized charge per case of $41,105. Based on the 622 MS–DRGs to which the technology mapped, the applicant computed a case-weighted threshold of $40,834. Because the total case-weighted average standardized charge per case of $41,105 exceeds the case weighted threshold of $40,834, the

applicant maintains that it meets the cost criteria.

We have several concerns regarding the applicant's cost analysis. First, although the technology can potentially be used in every single Medicare case, the application targets specific MS–DRGs. The applicant did not provide a detailed clinical justification regarding their selection of MS–DRGs, or a detailed justification for why the technology could not be used in other MS–DRGs. We believe it would be more appropriate to target all cases in every MS–DRG when conducting the cost analysis for this type of non-procedure or condition specific item. Using the FY 2011 AOR file, we conducted our own analysis with the same methodology above (and inflated the charges and included the total charges per stay related to the PerfectCLEAN) across all MS–DRGs. Based on our analysis, we determined a total case-weighted average standardized charge per case of $29,535. Using the applicant's methodology, we also determined a case-weighted threshold of $37,384 across all MS–DRGs. Because the total case-weighted average standardized charge per case of $29,535 is less than the case-weighted threshold of $37,384, we believe the PerfectCLEAN may not meet the cost criteria.

Second, the applicant included in the average charge per day more general charges unrelated to the specific new technology, such as payroll, packaging and protective gloves, laundering, storage and distribution. We do not believe it is appropriate to include charges for expenses already accounted for in MS–DRG based payments, such as laundering, storage, and distribution, and supplies already used by hospital staff such as packaging and protective gloves. We also note that the applicant states in its substantial clinical improvement discussion that the PerfectCLEAN represents the first comprehensive process for the removal and elimination of harmful micro-organisms responsible for HAIs from patient environments, the elimination of cross-contamination, and significant savings across many cost centers. If the PerfectCLEAN is a substitute for other cleaning mechanisms such as wiping down a hospital room with a spray and can produce significant savings across many cost centers, then it would be appropriate to deduct some charges from the average charge per day in order to accurately reflect the cost to hospitals of this technology. For these reasons, we remain concerned about the accuracy of the computation of a charge per patient of $100 per day and whether the PerfectCLEAN meets the cost criterion.

Thirdly, the applicant based the 12-percent, 2-year rate-of-change in charges on a 3-year average (FY 2009 through FY 2011) of the 2-year rate-of-change in charges as published in section II. of the Addendum to the annual IPPS final rule. We do not believe it is appropriate to use a 3-year average of the 2-year rate-of-change in charges as the 2-year rate-of-change in charges already uses the most recent data available to measure this change and, therefore, does not need to be averaged with prior years. Specifically, as described in section II. of the Addendum to this proposed rule, to calculate the proposed FY 2012 2-year rate-of-change in charges, we compared the 1-year average annualized rate-of-change in charges per case from the last quarter of FY 2009 in combination with the first quarter of FY 2010 (July 1, 2009 through December 31, 2009) to the last quarter of FY 2010 in combination with the first quarter of FY 2011 (July 1, 2010 through December 31, 2010). This rate-of-change was 4.43 percent (1.044394) or 9.07 percent (1.090759) over 2 years. If we substitute the FY 2012 proposed 2-year rate-of-change in charges of 9.07 percent for the 12-percent 3-year average of the 2-year rate-of-change in charges that the applicant used in its cost analysis, the total case-weighted average standardized charge per case would be $40,047 across the 622 MS–DRGs to which the applicant believes the technology would map. As mentioned above, the applicant computed a case-weighted threshold of $40,834. Because the total case-weighted average standardized charge per case of $40,047 is less than the case-weighted threshold of $40,834, it appears the applicant would not meet the cost criteria. We invite public comment on whether the PerfectCLEAN meets the cost criterion.

The applicant maintains that it meets the substantial clinical improvement criteria for the following reasons: The applicant believes the PerfectCLEAN significantly improves clinical outcomes for a patient population as compared to currently available treatments, decreases rate of subsequent diagnostic or therapeutic interventions, and decreases the number of future hospitalizations or physician visits. The applicant cited independent laboratory studies that set forth the level of removal and elimination of pathogens achieved by the PerfectCLEAN. The applicant stated that the PerfectCLEAN includes "more precise and focused patient room procedures that when properly applied utilize the textile and micro-denier efficacies" listed in the product's independent test reports. The applicant states that this results "in a safer patient environment where the likelihood of cross contamination is reasonable." The applicant included test report data for the product, which demonstrated a 99.99 percent effectiveness of removing pathogens such as MRSA and C diff. The applicant cited industry and clinical support to demonstrate that improved patient environment can save lives. The applicant also stated that PerfectCLEAN represents the first comprehensive process for the removal and elimination of harmful micro-organisms responsible for hospital acquired infections from patient environments, the elimination of cross-contamination, and significant savings across many cost centers. The applicant stated that this new innovative system delivers reliable and repeatable results not currently achieved using currently available protocols and products. The applicant provided the following example: a traditional method of disinfection is to apply liquid disinfectants, which the applicant stated typically requires a 10-minute dwell time (which in most cases is not completed by the hospital) and then wiping or mopping up the nonevaporated liquids. Compared to this method, the applicant asserts that the PerfectCLEAN first removes the micro-organisms from those surfaces using specially designed microscopic fibers. The applicant asserts that these pathogens are trapped in a formulation of a chlorine binding technology which eliminates the pathogens.

The applicant further asserts that the PerfectCLEAN maintains its disinfecting capability longer than other methods because the chlorine-binding technology is introduced at the pellet stage of fiber extrusion so that it is present throughout the fiber, as opposed to a finish or coating process that wears off as textiles are used and laundered. Additionally, the applicant asserts that the technology's non-leaching chlorination system recharges in the wash process by attracting and binding free molecules of chlorine. The applicant further asserts that in this way the PerfectCLEAN recharges back to its original strength and efficacy which allows it to work more rapidly than other techniques. The applicant asserts that this reduces cross-contamination by those persons handling soiled textiles after the people contact surfaces which have been cleaned of harmful micro-organisms. The applicant added that the training in use of color coated textiles (different color mats) affords superior monitoring and compliance supervision of the hygiene specialists charged with

responsibility to reduce cross-contamination. We invite public comment on whether the PerfectCLEAN meets the substantial clinical improvement criterion.

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

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts "for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level." In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2012 hospital wage index based on the statistical areas, including OMB's revised definitions of Metropolitan Areas, appears under section III.B. of this preamble.

Beginning October 1, 1993, section 1886(d)(3)(E) of the Act requires that we update the wage index annually. Furthermore, this section of the Act provides that the Secretary base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. The survey must exclude the wages and wage-related costs incurred in furnishing skilled nursing services. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2012 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed below in section III.H. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2012 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply beginning October 1, 2011 (the FY 2012 wage index) appears under section III.C. of this preamble.

B. Core-Based Statistical Areas for the Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. In accordance with the broad discretion under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we define hospital labor market areas based on the Core-Based Statistical Areas (CBSAs) established by OMB and announced in December 2003 (69 FR 49027). For a discussion of OMB's revised delineations of CBSAs and our implementation of the CBSA definitions, we refer readers to the preamble of the FY 2005 IPPS final rule (69 FR 49026 through 49032).

As with the FY 2011 final rule, in this FY 2012 proposed rule, we are proposing to provide that hospitals receive 100 percent of their wage index based upon the CBSA configurations. Specifically, for each hospital, we are proposing to determine a wage index for FY 2012 employing wage index data from hospital cost reports for cost reporting periods beginning during FY 2008 and using the CBSA labor market definitions. We consider CBSAs that are Metropolitan Statistical Areas (MSAs) to be urban, and CBSAs that are Micropolitan Statistical Areas as well as areas outside of CBSAs to be rural. In addition, it has been our longstanding policy that where an MSA has been divided into Metropolitan Divisions, we consider the Metropolitan Division to comprise the labor market areas for purposes of calculating the wage index (69 FR 49029) (regulations at § 412.64(b)(1)(ii)(A)).

In OMB Bulletin No. 10–2, issued on December 1, 2009, OMB announced that the CBSA changes in that bulletin would be the final update prior to the 2010 Census of Population and Housing. CMS adopted those changes in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50162), beginning October 1, 2010, and they are reflected in this FY 2012 proposed rule. In 2013, OMB plans to announce new area delineations based on its 2010 standards (75 FR 37246) and the 2010 Census data.

The OMB bulletin is available on the OMB Web site at *http://www.whitehouse.gov/OMB*—go to "Agency Information" and click on "Bulletins".

C. Proposed Occupational Mix Adjustment to the FY 2012 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Development of Data for the Proposed FY 2012 Occupational Mix Adjustment Based on the 2007–2008 Occupational Mix Survey

As provided for under section 1886(d)(3)(E) of the Act, we collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program.

For the FY 2010 hospital wage index, we used occupational mix data collected on a revised 2007–2008 Medicare Wage Index Occupational Mix Survey (the 2007–2008 survey) to compute the occupational mix adjustment for FY 2010. (We refer readers to the FY 2010 IPPS final rule (74 FR 43827) for a detailed discussion of the 2007–2008 survey.) Again, for the FY 2011 hospital wage index, we used data from the 2007–2008 survey (including revised data for 45 hospitals) to compute the FY 2011 adjustment.

For the FY 2012 hospital wage index, we are proposing to again use occupational mix data collected on the 2007–2008 Medicare Wage Index Occupational Mix Survey to compute the occupational mix adjustment for FY 2012. We are including data for 3,165 hospitals that also have wage data included in the proposed FY 2012 wage index.

2. New 2010 Occupational Mix Survey for the FY 2013 Wage Index

As stated earlier, section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We used occupational mix data collected on the 2007–2008 survey to compute the occupational mix adjustment for FY 2010 and the FY 2011 wage index and are proposing to use the 2007–2008 occupational mix survey data in this proposed rule for the FY 2012 wage index. Therefore, a new measurement of occupational mix will be required for FY 2013.

The new 2010 survey (Form CMS–10079 (2010)) provides for the collection of hospital-specific wages and hours data for calendar year 2010 (that is, payroll periods ending between January 1, 2010 and December 31, 2010) and will be applied beginning with the FY 2013 wage index. The 2010 survey was adopted in the **Federal Register** on January 15, 2010 (75 FR 2548) and approved by OMB on February 26, 2010 (OMB control number 0938–0907). The survey is available on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage* and through the fiscal intermediaries/MACs. Hospitals are required to submit their completed 2010 surveys to their fiscal intermediaries/MACs by July 1, 2011. The preliminary, unaudited 2010 survey data will be released in early October 2011, along with the FY 2009 Worksheet S–3 wage data, for the FY 2013 wage index review and correction process.

3. Calculation of the Proposed Occupational Mix Adjustment for FY 2012

For FY 2012 (as we did for FY 2011), we are proposing to calculate the occupational mix adjustment factor using the following steps:

Step 1—For each hospital, determine the percentage of the total nursing category attributable to a nursing subcategory by dividing the nursing subcategory hours by the total nursing category's hours. Repeat this computation for each of the four nursing subcategories: (1) Registered nurses; (2) licensed practical nurses; (3) nursing aides, orderlies, and attendants; and (4) medical assistants.

Step 2—Determine a national average hourly rate for each nursing subcategory by dividing a subcategory's total salaries for all hospitals in the occupational mix survey database by the subcategory's total hours for all hospitals in the occupational mix survey database.

Step 3—For each hospital, determine an adjusted average hourly rate for each nursing subcategory by multiplying the percentage of the total nursing category (from Step 1) by the national average hourly rate for that nursing subcategory (from Step 2). Repeat this calculation for each of the four nursing subcategories.

Step 4—For each hospital, determine the adjusted average hourly rate for the total nursing category by summing the adjusted average hourly rate (from Step 3) for each of the nursing subcategories.

Step 5—Determine the national average hourly rate for the total nursing category by dividing total nursing category salaries for all hospitals in the occupational mix survey database by total nursing category hours for all hospitals in the occupational mix survey database.

Step 6—For each hospital, compute the occupational mix adjustment factor for the total nursing category by dividing the national average hourly rate for the total nursing category (from Step 5) by the hospital's adjusted average hourly rate for the total nursing category (from Step 4).

If the hospital's adjusted average hourly rate is less than the national average hourly rate (indicating the hospital employs a less costly mix of nursing employees), the occupational mix adjustment factor is greater than 1.0000. If the hospital's adjusted average hourly rate is greater than the national average hourly rate, the occupational mix adjustment factor is less than 1.0000.

Step 7—For each hospital, calculate the occupational mix adjusted salaries and wage-related costs for the total nursing category by multiplying the hospital's total salaries and wage-related costs (from Step 5 of the unadjusted wage index calculation in section III.F. of this preamble) by the percentage of the hospital's total workers attributable to the total nursing category (using the occupational mix survey data, this percentage is determined by dividing the hospital's total nursing category salaries by the hospital's total salaries for "nursing and all other") and by the total nursing category's occupational mix adjustment factor (from Step 6 above).

The remaining portion of the hospital's total salaries and wage-related costs that is attributable to all other employees of the hospital is not adjusted by the occupational mix. A hospital's all other portion is determined by subtracting the hospital's nursing category percentage from 100 percent.

Step 8—For each hospital, calculate the total occupational mix adjusted salaries and wage-related costs for a hospital by summing the occupational mix adjusted salaries and wage-related costs for the total nursing category (from Step 7) and the portion of the hospital's salaries and wage-related costs for all other employees (from Step 7).

To compute a hospital's occupational mix adjusted average hourly wage, divide the hospital's total occupational mix adjusted salaries and wage-related costs by the hospital's total hours (from Step 4 of the unadjusted wage index calculation in section III.F. of this preamble).

Step 9—To compute the occupational mix adjusted average hourly wage for an urban or rural area, sum the total occupational mix adjusted salaries and wage-related costs for all hospitals in the area, then sum the total hours for all hospitals in the area. Next, divide the area's occupational mix adjusted salaries and wage-related costs by the area's hours.

Step 10—To compute the national occupational mix adjusted average hourly wage, sum the total occupational mix adjusted salaries and wage-related costs for all hospitals in the Nation, then sum the total hours for all hospitals in the Nation. Next, divide the national occupational mix adjusted salaries and wage-related costs by the national hours. The proposed FY 2012 occupational mix adjusted national average hourly wage is $36.1406.

Step 11—To compute the occupational mix adjusted wage index, divide each area's occupational mix adjusted average hourly wage (Step 9) by the national occupational mix adjusted average hourly wage (Step 10).

Step 12—To compute the Puerto Rico specific occupational mix adjusted wage index, follow Steps 1 through 11 above. The proposed FY 2012 occupational mix adjusted Puerto Rico-specific average hourly wage is $15.4107.

The table below is an illustrative example of the occupational mix adjustment.

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Example of Occupational Mix Adjustment

Hospital A								
			Step 1	Step 2	Step 3	Step 5	Step 6	in Step 7
	Provider Occupational Mix Hours	**Provider Occupational Mix Salaries**	**Provider % by Subcategory**	**National AHWs by Subcategory**	**Provider Adjusted AHW**	**National Adjusted Nurse AHW**	**Nurse Occupa-tional Mix Adjust-ment Factor**	**Provider % by Total**
Registered Nurses	1,642,129	18,125,763	**79.84%**	$40.00	**$31.94**			
Licensed Practical Nurses and Surgical Technologists	67,860	404,822	**3.30%**	$20.00	**$0.66**			
Nursing Aides, Orderlies, & Attendants	259,177	1,762,579	**12.60%**	$13.00	**$1.64**			
Medical Assistants	87,622	577,045	**4.26%**	$12.00	**$0.51**			
Total Nurse Hours and Salaries	**2,056,788**	**20,870,209**			**$34.75**	**$27.00**	**0.7771**	**52.40%**
					↗			
ALL OTHER	5,000,000	$18,957,010			Step 4			**47.60%**
TOTAL	**7,056,788**	**$39,827,219**						
Wage Data from Cost Report								
Wages (From S-3, Parts II and III)	$83,312,942.55							
Hours (From S-3, Parts II and III)	3,836,299.60							
Hospital A Unadjusted AHW	**$21.72**							
Nurse Occupational Mix Wages	**$33,925,838**	Step 7						
All Other Unadjusted Occupational Mix Wages	**$39,655,400**	Step 7						
Total Occupational Mix Wages	**$73,581,237**	Step 8						

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Hospital A Final Occupational Mix Adjusted AHW	**$19.18**	Step 8						
Hospital B								
			Step 1	Step 2	Step 3	Step 5	Step 6	in Step 7
	Provider Occupational Mix Hours	**Provider Occupational Mix Salaries**	**Provider % by Subcategory**	**National AHWs by Subcategory**	**Provider Adjusted AHW**	**National Adjusted Nurse AHW**	**Nurse Occupa-tional Mix Adjustment Factor**	**Provider % by Total**
Registered Nurses	1,142,129	18,125,763	**72.43%**	$30.00	**$21.73**			
Licensed Practical Nurses and Surgical Technologists	67,860	404,822	**4.30%**	$20.00	**$0.86**			
Nursing Aides, Orderlies, & Attendants	279,177	1,762,579	**17.71%**	$13.00	**$2.30**			
Medical Assistants	87,622	577,045	**5.56%**	$12.00	**$0.67**			
Total Nurse Hours and Salaries	**1,576,788**	**20,870,209**			**$25.56**	**$27.00**	**1.0564**	**52.40%**
					↗			
ALL OTHER	5,000,000	18,957,010			Step 4			**47.60%**
TOTAL	**6,576,788**	**$39,827,219**						
Wage Data from Cost Report								
Wages (From S-3, Parts II and III)	$25,979,714							
Hours (From S-3, Parts II and III)	1,097,585							
Hospital B Unadjusted AHW	**$23.67**							
Nurse Occupational Mix Wages	**$14,381,144**	Step 7						
All Other Unadjusted Occupational Mix Wages	**$12,365,857**	Step 7						
Total Occupational Mix Wages	**$26,747,001**	Step 8						
Hospital B Final Occupational Mix Adjusted AHW	**$24.37**	Step 8						
Note: The numbers in this example are hypothetical, including all National AHW amounts.								

Because the occupational mix adjustment is required by statute, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the proposed FY 2012 wage index. For the FY 2007–2008 survey, the response rate was 90.8 percent.

In computing the proposed FY 2012 wage index, if a hospital did not respond to the occupational mix survey, or if we determined that a hospital's submitted data were too erroneous to include in the wage index, we assigned the hospital the average occupational mix adjustment for its labor market area. This method has the least impact on the wage index for other hospitals in the area. For areas where no hospital submitted data for purposes of calculating the occupational mix adjustment, we applied the national occupational mix factor of 1.0000 in calculating the area's proposed FY 2012 occupational mix adjusted wage index. In addition, if a hospital submitted a survey, but that survey data could not be used because we determined the survey data to be aberrant, we also assigned the hospital the average occupational mix adjustment for its labor market area. For example, if a hospital's individual nurse category average hourly wages were out of range (that is, unusually high or low), and the hospital did not provide sufficient documentation to explain the aberrancy, or the hospital did not submit any registered nurse salaries or hours data, we assigned the hospital the average occupational mix adjustment for the labor market area in which it is located.

In calculating the average occupational mix adjustment factor for a labor market area, we replicated Steps 1 through 6 of the calculation for the occupational mix adjustment. However, instead of performing these steps at the hospital level, we aggregated the data at the labor market area level. In following these steps, for example, for CBSAs that contain providers that did not submit occupational mix survey data, the occupational mix adjustment factor ranged from a low of 0.9246 (CBSA 17780, College Station-Bryan, TX), to a high of 1.0761 (CBSA 19, Rural Louisiana). Also, in computing a hospital's occupational mix adjusted salaries and wage-related costs for nursing employees (Step 7 of the calculation), in the absence of occupational mix survey data, we multiplied the hospital's total salaries and wage-related costs by the percentage of the area's total workers attributable to the area's total nursing category. For FY 2012, there are five CBSAs (that include six hospitals) for which we did not have occupational mix data for any of its hospitals. The CBSAs are:

- CBSA 36140, Ocean City, NJ (1 hospital)
- CBSA 22140, Farmington, NM (1 hospital)
- CBSA 41900, San German-Cabo Rojo, PR (2 hospitals)
- CBSA 49500, Yauco, PR (1 hospital)
- CBSA 21940, Fajardo, PR (1 hospital)

Since the FY 2007 IPPS final rule, we have periodically discussed applying a hospital-specific penalty to hospitals that fail to submit occupational mix survey data (71 FR 48013 through 48014; 72 FR 47314 through 47315; 73 FR 48580; 74 FR 43832, and 75 FR 50167). During the FY 2008 rulemaking cycle, some commenters suggested a penalty equal to a 1- to 2-percent reduction in the hospital's wage index value or a set percentage of the standardized amount. During the FY 2009 and FY 2010 rulemaking cycles, several commenters reiterated their view that full participation in the occupational mix survey is critical, and that CMS should develop a methodology that encourages hospitals to report occupational mix survey data but does not unfairly penalize neighboring hospitals. We indicated in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule that, while we were not proposing a penalty at that time, we would consider the public comments we previously received, as well as any public comments on the proposed rule, as we developed the FY 2011 wage index.

In the FY 2011 IPPS/LTCH PPS proposed and final rules (75 FR 23943 and 50167, respectively), we stated that, in order to gain a better understanding of why some hospitals are not submitting the occupational mix data, we will require hospitals that do not submit occupational mix data to provide an explanation for not complying. This requirement will be effective beginning with the new 2010 occupational mix survey (the 2010 survey is discussed in section III.C.2. of this preamble). We will instruct fiscal intermediaries/MACs to begin gathering this information as part of the FY 2013 wage index desk review process. We note that we reserve the right to apply a different approach in future years, including potentially penalizing nonresponsive hospitals.

D. Worksheet S–3 Wage Data for the Proposed FY 2012 Wage Index

The proposed FY 2012 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2008 (the FY 2011 wage index was based on data from cost reporting periods beginning during FY 2007).

1. Included Categories of Costs

The proposed FY 2012 wage index includes the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty)
- Home office costs and hours
- Certain contract labor costs and hours (which includes direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315))
- Wage-related costs, including pensions and other deferred compensation costs.

2. Proposal for Changes to the Reporting Requirements for Pension Costs for the Medicare Wage Index

a. Background

The instructions for determining and reporting defined benefit pension costs on the cost report for Medicare cost-finding purposes are located in section 2142 of the Provider Reimbursement Manual, Part I (PRM–I). For Medicare wage index purposes, the instructions in section 3605.2 of the Provider Reimbursement Manual, Part II (PRM–II) for Worksheet S–3, Part II, Lines 13 through 20, require hospitals to comply with the requirements in section 2142 of the PRM–I.

Specifically, section 2142.5 of the PRM–I defines the current period liability for pension cost (that is, the maximum allowable pension cost) based on the actuarial accrued liability, normal cost, and unfunded actuarial liability. Under section 2142.4(A) of the PRM–I, these liability measurements are to be computed in accordance with the Employee Retirement Income Security Act of 1974 (ERISA), regardless of whether or not the pension plan is subject to ERISA. Also, section 2142.6(A) of the PRM–I requires the current period liability for pension costs to be funded in order to be allowable. In addition, section 2142.6(C) of the PRM–I allows for funding in excess of

the current period liability to be carried forward and recognized in future periods. We note that, on March 28, 2008, CMS published Revision 436, a technical clarification to section 2142 of the PRM–I.

Actuarial accrued liability and normal cost are typically determined on an ongoing plan basis using long-term, best-estimate assumptions. The interest assumption reflects the average rates of return expected over the period during which benefits were payable, taking into account the investment mix of plan assets. Pension costs for plans not subject to ERISA (such as church plans and plans sponsored by public sector employers) are also typically based on the actuarial accrued liability and normal cost using long-term, best estimate assumptions.

The Pension Protection Act (PPA) of 2006 (Pub. L. 109–280) amended ERISA. Under the PPA amendments to ERISA, the actuarial accrued liability and normal cost are no longer used as a basis for determining ERISA minimum required or maximum tax deductible contributions. ERISA contribution limits are now based on a "funding target" and "target normal cost" measured on a settlement basis using the current market interest rates for investment grade corporate bonds that match the duration of the benefit payouts. The Internal Revenue Service (IRS) publishes the applicable interest rate tables on a monthly basis. Because pension liabilities are very sensitive to changes in the interest rate used to discount future benefit payouts, pension costs based on the PPA "funding target" and "target normal cost" values are expected to be less stable than those based on the pre-PPA traditional long-term, best-estimate assumptions, which change infrequently. Furthermore, plans not subject to the ERISA requirements, as amended by the PPA, are not likely to use the new "funding target" and "target normal cost" basis for determining pension costs, and ERISA plans are not likely to continue to report costs developed using the actuarial accrued liability and normal cost based on long-term, best estimate assumptions. Accordingly, there is no longer a standard actuarial basis used by all plans.

In response to the PPA amendments to ERISA, we began a review of the rules for determining pension costs for Medicare cost finding and wage index purposes. As an interim measure, we issued a Joint Signature Memorandum (JSM) in November 2009 that contained instructions and a spreadsheet to assist hospitals and Medicare contractors in determining the annual allowable defined benefit pension cost for the FY 2011 wage index (JSM/TDL–10061, 11–20–09, December 3, 2009). Although these instructions were released for purposes of the wage index, these instructions also serve as interim guidance for Medicare cost-finding purposes.

In this proposed rule, we are proposing to revise our policy for determining pension cost for Medicare purposes. As mentioned above, due to the ERISA rules, as amended by the PPA, there is no longer a standard actuarial cost basis to be used by all types of plans. Therefore, we are proposing to no longer rely on actuarial computation to determine the maximum annual cost limitation for Medicare. Instead, the general parameters of our proposal would maintain the current requirement that pension costs must be funded to be reportable, and would require all hospitals to report the actual pension contributions funded during the reporting period, on a cash basis.

In addition, under this cash basis approach, we are proposing separate methodologies for measuring pension costs for Medicare cost-finding purposes (discussed in section IV.M. of this preamble) and for purposes of updating the wage index (discussed below in section III.D.2.b. of this preamble). We believe it is necessary to have two distinct proposals in order to address the different goals of determining a hospital's payments and updating the average hourly wage to establish the geographic area wage index. The function of the wage index is to measure relative hospital labor costs across areas. This function is distinct from Medicare payment determinations, where the goal is to measure the actual costs incurred by individual hospitals. These two distinct proposals would require separate updated instructions to section 2142 of the PRM–I for Medicare cost-finding purposes and section 3605.2 of the PRM–II for purposes of the wage index. Below is a detailed discussion of our proposal for reporting pension costs under the wage index. A full discussion of our proposal for Medicare cost-finding is discussed in section IV.M. of this preamble.

The proposal below reflects our commitment to the general principles of the President's Executive Order released January 18, 2011, entitled "Improving Regulation and Regulatory Review."

b. Proposal for Allowable Pension Cost for the Medicare Wage Index

As mentioned above, the function of the Medicare wage index is to measure relative hospital labor costs across all areas. Therefore, while we believe pension costs must be funded in order to be reportable (we refer readers to the August 12, 2010 **Federal Register** (74 FR 47369) for an explanation of this longstanding policy), it also is important for pension costs to be relatively stable from year to year so that there is less volatility in the wage index. Thus, we are proposing to include, in the wage index, pension costs equal to the average actual cash contributions deposited to a hospital's defined benefit pension plan by the hospital and/or the hospital system over a 3-year period. The use of cash contributions as a measure of the costs incurred is necessary to ensure uniformity among all hospitals, regardless of their tax status or ERISA coverage. The 3-year average is intended to reduce the volatility that often occurs due to timing of contributions. Most pension plan sponsors have flexibility to determine the pension funding for a particular period and their decisions may be based on cash-flow considerations or other factors unrelated to the normal operation of the plan. Furthermore, the funding of current period pension costs may be delayed by almost a full year after the close of the period to which it applies. By using a 3-year average, we hope to enhance the stability of the wage index.

To ensure that the average annual pension cost reflected in the wage index is consistent with the reporting period applicable to all other costs included in the index, we are proposing that the 3-year average be centered on the base cost reporting year for the wage index. For example, the FY 2013 wage index will be based on Medicare cost reporting periods beginning during FY 2009 and would reflect the average pension contributions made in hospitals' cost reporting periods beginning during FYs 2008, 2009, and 2010. Thus, this proposal would require pension plan contribution data for the cost reporting periods immediately preceding and immediately following the base cost reporting period for the wage index.

We do not anticipate that the use of contributions made in the cost reporting period immediately following the reporting year will create an administrative burden because, even under the existing rule, contributions to fund current period costs are often deferred until the following period. In addition, trust account statements and general ledger reports to support the contributions should be readily available. We are proposing to apply the above methodology for reporting pension costs for the wage index beginning with the FY 2013 IPPS update. We invite public comment on

this policy proposal and are especially interested in receiving comments related to the proposed 3-year averaging period.

3. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2011, the proposed wage index for FY 2012 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as SNF services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2012 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index, for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397).

4. Use of Wage Index Data by Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index are also currently used to calculate wage indices applicable to other providers, such as SNFs, home health agencies (HHAs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indices for non-IPPS providers, other than for LTCHs. Such comments should be made in response to separate proposed rules for those providers.

E. Verification of Worksheet S–3 Wage Data

The wage data for the proposed FY 2012 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report for cost reporting periods beginning on or after October 1, 2007, and before October 1, 2008. For wage index purposes, we refer to cost reports during this period as the "FY 2008 cost report," the "FY 2008 wage data," or the "FY 2008 data." Instructions for completing Worksheet S–3, Parts II and III are in the Provider Reimbursement Manual (PRM), Part II, sections 3605.2 and 3605.3. The data file used to construct the proposed wage index includes FY 2008 data submitted to us as of March 3, 2011. As in past years, we performed an intensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries/MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2012 wage index, we identified and excluded 23 providers with data that was too aberrant to include in the proposed wage index, although if data elements for some of these providers are corrected, we intended to include some of these providers in the FY 2012 final wage index. We instructed fiscal intermediaries/MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than April 13, 2011. We intend that all unresolved data elements will be resolved by the date the final rule is issued. The revised data will be reflected in the FY 2012 IPPS final rule.

In constructing the proposed FY 2012 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2008, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397). For this proposed rule, we removed 19 hospitals that converted to CAH status between February 16, 2010, the cut-off date for CAH exclusion from the FY 2011 wage index, and February 15, 2011, the cut-off date for CAH exclusion from the FY 2012 wage index. After removing hospitals with aberrant data and hospitals that converted to CAH status, the proposed FY 2012 wage index is calculated based on 3,484 hospitals.

In the FY 2008 final rule with comment period (72 FR 47317) and the FY 2009 IPPS final rule (73 FR 48582), we discussed our policy for allocating a multicampus hospital's wages and hours data, by full-time equivalent (FTE) staff, among the different labor market areas where its campuses are located. During the FY 2011 wage index desk review process, we requested fiscal intermediaries/MACs to contact multicampus hospitals that had campuses in different labor market areas to collect the data for the allocation. The FY 2011 wage index included separate wage data for campuses of three multicampus hospitals.

For FY 2012, as we discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50168), we are proposing to no longer allow hospitals to use discharge data for the allocation of a multicampus hospital's wage data among the different labor market areas where its campuses are located. The Medicare cost report was updated in May 2008 to provide for the reporting of FTE data by campus for multicampus hospitals (Form CMS–2552–96, Worksheet S–2, lines 61 and 62). The data from cost reporting periods that begin in FY 2008 are now available for calculating the wage index for FY 2012. Therefore, a multicampus hospital will not have the option to use either FTE or discharge data for allocating wage data among its campuses by providing the information from the applicable cost reporting period to CMS through its fiscal intermediary/MAC. The table containing the proposed FY 2012 wage index, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, includes separate wage data for campuses of three multicampus hospitals.

F. Method for Computing the Proposed FY 2012 Unadjusted Wage Index

1. Steps for Computation

The method used to compute the proposed FY 2012 wage index without an occupational mix adjustment follows:

Step 1—As noted above, we are proposing to base the proposed FY 2012 wage index on wage data reported on the FY 2008 Medicare cost reports. We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period beginning on or after October 1, 2007, and before October 1, 2008. In addition, we included data from some hospitals that had cost reporting periods beginning before October 2007 and reported a cost reporting period covering all of FY 2008. These data are included because no other data from these hospitals would be available for the cost reporting period described above, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2008 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2008 (for example, a hospital had two short cost reporting

periods beginning on or after October 1, 2007, and before October 1, 2008), we included wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2—Salaries—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we include Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II for overhead services in the wage index. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation for FY 2011 is to compute a "revised" Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 22.01, 26.01, and 27.01.) In calculating a hospital's average salaries plus wage-related costs, we subtract from Line 1 (total salaries) the GME and CRNA costs reported on Lines 2, 4.01, 6, and 6.01, the Part B salaries reported on Lines 3, 5 and 5.01, home office salaries reported on Line 7, and exclude salaries reported on Lines 8 and 8.01 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. To determine total salaries plus wage-related costs, we add to the net hospital salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 9 and 10), home office salaries and wage-related costs reported by the hospital on Lines 11 and 12, and nonexcluded area wage-related costs (Lines 13, 14, and 18).

We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 18) are excluded if no corresponding salaries are reported for those employees on Line 4.

Step 3—Hours—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2.

Step 4—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ratio of excluded area hours (sum of Lines 8 and 8.01 of Worksheet S–3, Part II) to revised total hours (Line 1 minus the sum of Part II, Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, and Part III, Line 13 of Worksheet S–3). We then compute the amounts of overhead salaries and hours to be allocated to excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Line 13 of Worksheet S–3, Part III. Next, we compute the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determine the ratio of overhead hours (Part III, Line 13 minus the sum of Lines 22.01, 26.01, and 27.01) to revised hours excluding the sum of Lines 22.01, 26.01, and 27.01 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, 8, 8.01, 22.01, 26.01, and 27.01). (We note that for the FY 2008 and subsequent wage index calculations, we are excluding the sum of Lines 22.01, 26.01, and 27.01 from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 22.01, 26.01, and 27.01 require that associated wage-related costs be combined with wages on the respective contract labor lines.); (2) we compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 13, 14, and 18; and (3) we multiply the computed overhead wage-related costs by the above excluded area hours ratio. Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2005, through April 15, 2007, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing to make any changes to the usage for FY 2012. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2007	11/15/2007	1.03990
11/14/2007	12/15/2007	1.03699
12/14/2007	01/15/2008	1.03402
01/14/2008	02/15/2008	1.03113
02/14/2008	03/15/2008	1.02831
03/14/2008	04/15/2008	1.02555
04/14/2008	05/15/2008	1.02286
05/14/2008	06/15/2008	1.02024
06/14/2008	07/15/2008	1.01766
07/14/2008	08/15/2008	1.01511
08/14/2008	09/15/2008	1.01258
09/14/2008	10/15/2008	1.01015
10/14/2008	11/15/2008	1.00787
11/14/2008	12/15/2008	1.00575
12/14/2008	01/15/2009	1.00375
01/14/2009	02/15/2009	1.00183
02/14/2009	03/15/2009	1.00000
03/14/2009	04/15/2009	0.99820

For example, the midpoint of a cost reporting period beginning January 1, 2008, and ending December 31, 2008, is June 30, 2008. An adjustment factor of 1.01766 would be applied to the wages of a hospital with such a cost reporting period. In addition, for the data for any cost reporting period that began in FY 2008 and covered a period of less than 360 days or more than 370 days, we annualize the data to reflect a 1-year cost report. Dividing the data by the number of days in the cost report and then multiplying the results by 365 accomplishes annualization.

Step 6—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), section 1886(d)(8)(E), or section 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7—We divide the total adjusted salaries plus wage-related costs obtained under both methods in Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage. Using the data as described above, the proposed national average hourly wage (unadjusted for occupational mix) is $36.1697.

Step 9—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10—Following the process set forth above, we develop a separate Puerto Rico-specific wage index for purposes of adjusting the Puerto Rico standardized amounts. (The national Puerto Rico standardized amount is adjusted by a wage index calculated for all Puerto Rico labor market areas based on the national average hourly wage as described above.) We add the total adjusted salaries plus wage-related costs (as calculated in Step 5) for all hospitals in Puerto Rico and divide the sum by the total hours for Puerto Rico (as calculated in Step 4) to arrive at an overall proposed average hourly wage (unadjusted for occupational mix) of $15.3863 for Puerto Rico. For each labor market area in Puerto Rico, we calculate the Puerto Rico-specific wage index value by dividing the area average hourly wage (as calculated in Step 7) by the overall Puerto Rico average hourly wage.

Step 11—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 4D which is listed in section VI. of the Addendum to this proposed rule and available via the Internet.

2. Expiration of the Imputed Floor Policy

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the "imputed" floor as a temporary 3-year regulatory measure to address a concern by some individuals that hospitals in all-urban States were disadvantaged by the absence of rural hospitals to set a wage index floor in those States. There are two States that have no rural areas (New Jersey and Rhode Island). Rhode Island has only one urban area. In accordance with the imputed floor calculation (§ 412.64(h)(4) of the regulations), Rhode Island receives no benefit from the policy. As a result, the imputed floor policy only benefits one State—New Jersey. Although New Jersey may argue that it is disadvantaged by

the statutory rural floor because it has no rural areas, the imputed floor policy provides New Jersey with a guaranteed benefit that no other State has. In any given year, approximately one-half of the States have no hospitals that benefit from the rural floor provision. However, New Jersey benefits each year that the imputed floor policy is in place.

The imputed floor was originally set to expire in FY 2007, but we extended it an additional year in the FY 2008 IPPS final rule with comment period (72 FR 47321). In the FY 2009 IPPS final rule (73 FR 48570 through 48574 and 48584), we extended the imputed floor for an additional 3 years, through FY 2011, linking the extension to a policy to apply budget neutrality for the rural and imputed floors within each State, instead of nationally, over a 3-year transition period. Section 3141 of the Affordable Care Act replaced the statewide budget neutrality policy with the national budget neutrality policy that was in place during FY 2008. That is, section 3141 required that budget neutrality for the rural and imputed floor be applied "through a uniform, national adjustment to the area wage index" instead of within each State beginning in FY 2011 (75 FR 50160). However, we note that the Affordable Care Act did not include a provision to extend the imputed floor or to make the imputed floor permanent. Therefore, the imputed floor is set to expire with the FY 2011 wage index, and we are not proposing to extend the imputed floor policy. Thus, the imputed floor is not reflected in the table containing the proposed FY 2012 wage index, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet.

As we discussed in the FY 2008 IPPS proposed rule and final rule with comment period (72 FR 24786 and 72 FR 47322, respectively), the application of the national budget neutrality requirement for the rural and imputed floors requires a transfer of payments from hospitals in States with rural hospitals but where the rural floor is not applied to hospitals in States where the rural or imputed floor is applied. For this reason, we believe that the floor policy should apply only when required by statute. Thus, only States containing both rural areas and hospitals located in such areas (including any hospital reclassified as rural under § 412.103) would benefit from the rural floor, as required by section 4410 of Public Law 105–33.

In the proposed FY 2012 wage index, the rural floor will apply to 189 hospitals in 26 States. If the imputed floor policy was to continue into FY 2012, it would apply to 39 additional hospitals in New Jersey. We are seeking public comments regarding the expiration of the imputed floor.

3. Proposed FY 2012 Puerto Rico Wage Index

We note that, for the proposed FY 2012 wage index, there is one new hospital in rural Puerto Rico when previously there were none. However, this hospital has no cost reporting period beginning during FY 2008 and, therefore, has no wage data for inclusion in the proposed FY 2012 wage index calculation for rural Puerto Rico. We discussed in the FY 2005 IPPS final rule that, under these circumstances, we would determine a State's rural floor based on the imputed floor policy in § 412.64(h)(4) of the regulations. However, as discussed above, the imputed floor is set to expire with the FY 2011 wage index. We adopted the policy in the FY 2008 IPPS final rule with comment period (72 FR 47323) that if there are no hospitals' cost report wage data available to calculate a State's rural floor, and the imputed floor policy has expired, "we will use the unweighted average of the wage indices from all CBSAs (urban areas) that are contiguous to the rural counties of the State to compute the State's rural floor. (We define contiguous as sharing a border.)" Except for Fajardo, Puerto Rico (CBSA 21940), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2012 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2012 wage indices for the following urban areas: Aguadilla-Isabela-San Sebastián, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayagüez, PR (CBSA 32420); Ponce, PR (CBSA 38660), San Germán-Cabo Rojo, PR (CBSA 41900), San Juan-Caguas-Guaynabo, PR (CBSA 41980), and Yauco, PR (CBSA 49500).

G. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2012 Occupational Mix Adjusted Wage Index

As discussed in section III.C. of this preamble, for FY 2012, we are proposing to apply the occupational mix adjustment to 100 percent of the proposed FY 2012 wage index. We calculated the proposed occupational mix adjustment using data from the 2007–2008 occupational mix survey data, using the methodology described in section III.C.3. of this preamble.

Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the proposed FY 2012 wage index results in a proposed national average hourly wage of $36.1406 and a proposed Puerto-Rico specific average hourly wage of $15.4107. After excluding data of hospitals that either submitted aberrant data that failed critical edits, or that do not have FY 2008 Worksheet S–3 cost report data for use in calculating the proposed FY 2012 wage index, we calculated the proposed FY 2012 wage index using the occupational mix survey data from 3,165 hospitals. Using the Worksheet S–3 cost report data of 3,484 hospitals and occupational mix survey data from 3,165 hospitals represents a 90.8 percent survey response rate. The proposed FY 2012 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	36.049427439
National LPN and Surgical Technician	20.850540193
National Nurse Aide, Orderly, and Attendant	14.611398009
National Medical Assistant	16.458374237
National Nurse Category	30.442540295

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $30.442540295. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of

greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2007–2008 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 44.31 percent, and the national percentage of hospital employees in the all other occupations category is 55.69 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 29.08 percent in one CBSA, to a high of 70.76 percent in another CBSA.

We compared the proposed FY 2012 occupational mix adjusted wage indices for each CBSA to the proposed unadjusted wage indices for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the proposed wage index values for 209 (53.6 percent) urban areas and 32 (66.7 percent) rural areas would increase. One hundred seven (27.4 percent) urban areas would increase by 1 percent or more, and 5 (1.3 percent) urban areas would increase by 5 percent or more. Seventeen (35.4 percent) rural areas would increase by 1 percent or more, and no rural areas would increase by 5 percent or more. However, the wage index values for 181 (46.4 percent) urban areas and 16 (33.3 percent) rural areas would decrease. Eighty-eight (22.6 percent) urban areas would decrease by 1 percent or more, and no urban area would decrease by 5 percent or more. Seven (14.6 percent) rural areas would decrease by 1 percent or more, and no rural areas would decrease by 5 percent or more. The largest positive impacts are 7.81 percent for an urban area and 2.90 percent for a rural area. The largest negative impacts are 3.95 percent for an urban area and 2.78 percent for a rural area. No urban or rural areas are unaffected. These results indicate that a larger percentage of rural areas (66.7 percent) would benefit from the occupational mix adjustment than do urban areas (53.6 percent). While these results are more positive overall for rural areas than under the previous occupational mix adjustment that used survey data from 2006, approximately one-third (33.3 percent) of rural CBSAs would still experience a decrease in their wage indices as a result of the occupational mix adjustment.

The proposed wage index values for FY 2012 (except those for hospitals receiving wage index adjustments under section 1886(d)(13) of the Act) included in Tables 4A, 4B, 4C, and 4F, which are listed in section VI. of the Addendum to this proposed rule and available via the Internet, include the proposed occupational mix adjustment.

Tables 3A and 3B, which are listed in section VI. of the Addendum to this proposed rule and available via the Internet, list the 3-year average hourly wage for each labor market area before the redesignation or reclassification of hospitals based on FYs 2010, 2011, and 2012 cost reporting periods. Table 3A lists these data for urban areas, and Table 3B lists these data for rural areas. In addition, Table 2, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, includes the adjusted average hourly wage for each hospital from the FY 2006 and FY 2007 cost reporting periods, as well as the FY 2008 period used to calculate the proposed FY 2012 wage index. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period. The proposed average hourly wages in Tables 2, 3A, and 3B, which are listed in section VI. of the Addendum to this proposed rule and available via the Internet, include the proposed occupational mix adjustment. The proposed wage index values in Tables 4A, 4B, 4C, and 4D also include the proposed national rural floor budget neutrality adjustment.

H. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify 13 months prior to the start of the fiscal year for which reclassification is sought (generally by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion of the proximity requirements in the FY 2002 IPPS final rule (66 FR 39874 and 39875).)

Section 1886(d)(10)(D)(v) of the Act provides that, beginning with FY 2001, a MGCRB decision on a hospital reclassification for purposes of the wage index is effective for 3 fiscal years, unless the hospital elects to terminate the reclassification. Section 1886(d)(10)(D)(vi) of the Act provides that the MGCRB must use average hourly wage data from the 3 most recently published hospital wage surveys in evaluating a hospital's reclassification application for FY 2003 and any succeeding fiscal year.

Section 304(b) of Public Law 106–554 provides that the Secretary must establish a mechanism under which a statewide entity may apply to have all of the geographic areas in the State treated as a single geographic area for purposes of computing and applying a single wage index, for reclassifications beginning in FY 2003. The implementing regulations for this provision are located at 42 CFR 412.235.

Section 1886(d)(8)(B) of the Act requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the labor market area to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area under the standards for designating MSAs and if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of *all* contiguous MSAs. In light of the CBSA definitions and the Census 2000 data that we implemented for FY 2005 (69 FR 49027), we undertook to identify those counties meeting these criteria. Eligible counties are discussed and identified under section III.H.5. of this preamble.

2. Effects of Reclassification/ Redesignation

Section 1886(d)(8)(C) of the Act provides that the application of the wage index to redesignated hospitals is dependent on the hypothetical impact that the wage data from these hospitals would have on the wage index value for the area to which they have been redesignated. These requirements for determining the wage index values for

redesignated hospitals are applicable both to the hospitals deemed urban under section 1886(d)(8)(B) of the Act and hospitals that were reclassified as a result of the MGCRB decisions under section 1886(d)(10) of the Act. Therefore, as provided in section 1886(d)(8)(C) of the Act, the wage index values were determined by considering the following:

- If including the wage data for the redesignated hospitals would reduce the wage index value for the area to which the hospitals are redesignated by 1 percentage point or less, the area wage index value determined exclusive of the wage data for the redesignated hospitals applies to the redesignated hospitals.
- If including the wage data for the redesignated hospitals reduces the wage index value for the area to which the hospitals are redesignated by more than 1 percentage point, the area wage index determined inclusive of the wage data for the redesignated hospitals (the combined wage index value) applies to the redesignated hospitals.
- If including the wage data for the redesignated hospitals increases the wage index value for the urban area to which the hospitals are redesignated, both the area and the redesignated hospitals receive the combined wage index value. Otherwise, the hospitals located in the urban area receive a wage index excluding the wage data of hospitals redesignated into the area.
- Rural areas whose wage index values would be reduced by excluding the wage data for hospitals that have been redesignated to another area continue to have their wage index values calculated as if no redesignation had occurred (otherwise, redesignated rural hospitals are excluded from the calculation of the rural wage index). The wage index value for a redesignated rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located.

CMS also has adopted the following policies:

- The wage data for a reclassified urban hospital is included in both the wage index calculation of the urban area to which the hospital is reclassified (subject to the rules described above) and the wage index calculation of the urban area where the hospital is physically located.
- In cases where hospitals have reclassified to rural areas, such as urban hospitals reclassifying to rural areas under 42 CFR 412.103, the hospital's wage data are: (a) included in the rural wage index calculation, unless doing so would reduce the rural wage index; and (b) included in the urban area where the hospital is physically located. The effect of this policy, in combination with the statutory requirement at section 1886(d)(8)(C)(ii) of the Act, is that rural areas may receive a wage index based upon the highest of: (1) Wage data from hospitals geographically located in the rural area; (2) wage data from hospitals geographically located in the rural area, but excluding all data associated with hospitals reclassifying out of the rural area under section 1886(d)(8)(B) or section 1886(d)(10) of the Act; or (3) wage data associated with hospitals geographically located in the area plus all hospitals reclassified into the rural area.

In addition, in accordance with the statutory language referring to "hospitals" in the plural under sections 1886(d)(8)(C)(i) and 1886(d)(8)(C)(ii) of the Act, our longstanding policy is to consider reclassified hospitals as a group when deciding whether to include or exclude them from both urban and rural wage index calculations.

3. FY 2012 MGCRB Reclassifications

a. FY 2012 Reclassification Requirements and Approvals

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in 42 CFR 412.230 through 412.280.

At the time this proposed rule was constructed, the MGCRB had completed its review of FY 2012 reclassification requests. Based on such reviews, there were 280 hospitals approved for wage index reclassifications by the MGCRB for FY 2012. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2012, hospitals reclassified during FY 2010 or FY 2011 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications. There were 283 hospitals approved for wage index reclassifications in FY 2010 and 294 hospitals approved for wage index reclassifications in FY 2011. Of all of the hospitals approved for reclassification for FY 2010, FY 2011, and FY 2012, based upon the review at the time of this proposed rule, 857 hospitals are in a reclassification status for FY 2012.

Under 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of a proposed rule. Generally stated, the request for withdrawal of an application for reclassification or termination of an existing 3-year reclassification that would be effective in FY 2012 has to be received by the MGCRB within 45 days of the publication of the proposed rule. Hospitals also may cancel prior reclassification withdrawals or terminations in certain circumstances. For further information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer the reader to 42 CFR 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887) and the FY 2003 IPPS final rule (67 FR 50065). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and "fallback" reclassifications, were included in the FY 2008 IPPS final rule (72 FR 47333).

Changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2012 will be incorporated into the wage index values published in the FY 2012 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

b. Applications for Reclassifications for FY 2013

Applications for FY 2013 reclassifications are due to the MGCRB by September 1, 2011. We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2011, via the CMS Internet Web site at: *http://cms.hhs.gov/MGCRB/02_instructions_and_applications.asp,* or by calling the MGCRB at (410) 786–1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244–2670.

4. Redesignations of Hospitals Under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B) of the Act requires us to treat a hospital located in a rural county adjacent to one or more

urban areas as being located in the MSA if certain criteria are met. Effective beginning FY 2005, we use OMB's 2000 CBSA standards and the Census 2000 data to identify counties in which hospitals qualify under section 1886(d)(8)(B) of the Act to receive the wage index of the urban area. Hospitals located in these counties have been known as "Lugar" hospitals and the counties themselves are often referred to as "Lugar" counties. We provide the FY 2011 chart below with the listing of the rural counties containing the hospitals designated as urban under section 1886(d)(8)(B) of the Act. For discharges occurring on or after October 1, 2011, hospitals located in the rural county in the first column of this chart will be redesignated for purposes of using the wage index of the urban area listed in the second column.

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Rural Counties Containing Hospitals Redesignated as Urban under Section 1886(d)(8)(B) of the Act (Based on CBSAs and Census 2000 Data)

Rural County	CBSA
Cherokee, AL	Rome, GA
Macon, AL	Auburn-Opelika, AL
Talladega, AL	Anniston-Oxford, AL
Hot Springs, AR	Hot Springs, AR
Windham, CT	Hartford-West Hartford-East Hartford, CT
Bradford, FL	Gainesville, FL
Hendry, FL	West Palm Beach-Boca Raton-Boynton, FL
Levy, FL	Gainesville, FL
Walton, FL	Fort Walton Beach-Crestview-Destin, FL
Banks, GA	Gainesville, GA
Chattooga, GA	Chattanooga, TN-GA
Jackson, GA	Atlanta-Sandy Springs-Marietta, GA
Lumpkin, GA	Atlanta-Sandy Springs-Marietta, GA
Morgan, GA	Atlanta-Sandy Springs-Marietta, GA
Peach, GA	Macon, GA
Polk, GA	Atlanta-Sandy Springs-Marietta, GA
Talbot, GA	Columbus, GA-AL
Bingham, ID	Idaho Falls, ID
Christian, IL	Springfield, IL
DeWitt, IL	Bloomington-Normal, IL
Iroquois, IL	Kankakee-Bradley, IL
Logan, IL	Springfield, IL
Mason, IL	Peoria, IL
Ogle, IL	Rockford, IL
Clinton, IN	Lafayette, IN
Henry, IN	Indianapolis-Carmel, IN
Spencer, IN	Evansville, IN-KY
Starke, IN	Gary, IN
Warren, IN	Lafayette, IN
Boone, IA	Ames, IA
Buchanan, IA	Waterloo-Cedar Falls, IA
Cedar, IA	Iowa City, IA
Allen, KY	Bowling Green, KY
Assumption Parish, LA	Baton Rouge, LA
St. James Parish, LA	Baton Rouge, LA
Allegan, MI	Holland-Grand Haven, MI
Montcalm, MI	Grand Rapids-Wyoming, MI
Oceana, MI	Muskegon-Norton Shores, MI
Shiawassee, MI	Lansing-East Lansing, MI

Rural County	CBSA
Tuscola, MI	Saginaw-Saginaw Township North, MI
Fillmore, MN	Rochester, MN
Dade, MO	Springfield, MO
Pearl River, MS	Gulfport-Biloxi, MS
Caswell, NC	Burlington, NC
Davidson, NC	Greensboro-High Point, NC
Granville, NC	Durham, NC
Harnett, NC	Raleigh-Cary, NC
Lincoln, NC	Charlotte-Gastonia-Concord, NC-SC
Polk, NC	Spartanburg, SC
Los Alamos, NM	Santa Fe, NM
Lyon, NV	Carson City, NV
Cayuga, NY	Syracuse, NY
Columbia, NY	Albany-Schenectady-Troy, NY
Genesee, NY	Rochester, NY
Greene, NY	Albany-Schenectady-Troy, NY
Schuyler, NY	Ithaca, NY
Sullivan, NY	Poughkeepsie-Newburgh-Middletown, NY
Wyoming, NY	Buffalo-Niagara Falls, NY
Ashtabula, OH	Cleveland-Elyria-Mentor, OH
Champaign, OH	Springfield, OH
Columbiana, OH	Youngstown-Warren-Boardman, OH-PA
Cotton, OK	Lawton, OK
Linn, OR	Corvallis, OR
Adams, PA	York-Hanover, PA
Clinton, PA	Williamsport, PA
Greene, PA	Pittsburgh, PA
Monroe, PA	Allentown-Bethlehem-Easton, PA-NJ
Schuylkill, PA	Reading, PA
Susquehanna, PA	Binghamton, NY
Clarendon, SC	Sumter, SC
Lee, SC	Sumter, SC
Oconee, SC	Greenville, SC
Union, SC	Spartanburg, SC
Meigs, TN	Cleveland, TN
Bosque, TX	Waco, TX
Falls, TX	Waco, TX
Fannin, TX	Dallas-Plano-Irving, TX
Grimes, TX	College Station-Bryan, TX
Harrison, TX	Longview, TX
Henderson, TX	Dallas-Plano-Irving, TX
Milam, TX	Austin-Round Rock, TX
Van Zandt, TX	Dallas-Plano-Irving, TX

Rural County	CBSA
Willacy, TX	Brownsville-Harlingen, TX
Buckingham, VA	Charlottesville, VA
Floyd, VA	Blacksburg-Christiansburg-Radford, VA
Middlesex, VA	Virginia Beach-Norfolk-Newport News, VA
Page, VA	Harrisonburg, VA
Shenandoah, VA	Winchester, VA-WV
Island, WA	Seattle-Bellevue-Everett, WA
Mason, WA	Olympia, WA
Wahkiakum, WA	Longview, WA
Jackson, WV	Charleston, WV
Roane, WV	Charleston, WV
Green, WI	Madison, WI
Green Lake, WI	Fond du Lac, WI
Jefferson, WI	Milwaukee-Waukesha-West Allis, WI
Walworth, WI	Milwaukee-Waukesha-West Allis, WI

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As in the past, hospitals redesignated under section 1886(d)(8)(B) of the Act are also eligible to be reclassified to a different area by the MGCRB. Affected hospitals are permitted to compare the reclassified wage index for the labor market area in Table 4C (which is listed in section VI. of the Addendum to this proposed rule and available via the Internet) into which they would be reclassified by the MGCRB to the wage index for the area to which they are redesignated under section 1886(d)(8)(B) of the Act. Hospitals may withdraw from an MGCRB reclassification within 45 days of the publication of this proposed rule.

5. Reclassifications Under Section 1886(d)(8)(B) of the Act

As discussed in the FY 2009 IPPS final rule (73 FR 48588), Lugar hospitals are treated like reclassified hospitals for purposes of determining their applicable wage index and receive the reclassified wage index for the urban area to which they have been redesignated. Because Lugar hospitals are treated like reclassified hospitals, when they are seeking reclassification by the MGCRB, they are subject to the rural reclassification rules set forth at 42 CFR 412.230. The procedural rules set forth at § 412.230 list the criteria that a hospital must meet in order to reclassify as a rural hospital. Lugar hospitals are subject to the proximity criteria and payment thresholds that apply to rural hospitals. Specifically, the hospital must be no more than 35 miles from the area to which it seeks reclassification (§ 412.230(b)(1)); and the hospital must show that its average hourly wage is at least 106 percent of the average hourly wage of all other hospitals in the area in which the hospital is located (§ 412.230(d)(1)(iii)(C)). In accordance with the requirements of section 3137(c) of the Affordable Care Act, beginning with reclassifications for the FY 2011 wage index, a Lugar hospital must also demonstrate that its average hourly wage is equal to at least 82 percent of the average hourly wage of hospitals in the area to which it seeks redesignation (§ 412.230(d)(1)(iv)(C)).

Hospitals not located in a Lugar county seeking reclassification to the urban area where the Lugar hospitals have been redesignated are not permitted to measure to the Lugar county to demonstrate proximity (no more than 15 miles for an urban hospital, and no more than 35 miles for a rural hospital or the closest urban or rural area for RRCs or SCHs) in order to be reclassified to such urban area. These hospitals must measure to the urban area exclusive of the Lugar County to meet the proximity or nearest urban or rural area requirement. We treat New England deemed counties in a manner consistent with how we treat Lugar counties. (We refer readers to FY 2008 IPPS final rule with comment period (72 FR 47337) for a discussion of this policy.)

6. Reclassifications Under Section 508 of Public Law 108–173

Section 508 of Public Law 108–173 allowed certain qualifying hospitals to receive wage index reclassifications and assignments that they otherwise would not have been eligible to receive under the law. Although section 508 originally was scheduled to expire after a 3-year period, Congress extended the provision several times, as well as certain special exceptions that would have otherwise expired. For a discussion of the original section 508 provision and its various extensions, we refer readers to the FY 2010 notice issued in the **Federal Register** on June 2, 2010 (75 FR 31118). Prior to the enactment of the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309) on December 15, 2010, the extension of the 508 provision was included in sections 3137(a) and 10317 of the Affordable Care Act (Pub. L. 111–148). Section 3137 of the Affordable Care Act extended, through FY 2010, section 508 reclassifications as well as certain special exceptions. The most recent extension of the provision was included in section 102 of the Medicare and Medicaid Extender Act, which extends, through FY 2011, section 508 reclassifications as well as certain special exceptions. The latest extension of these provisions expires on September 30, 2011, and will no longer be applicable effective with FY 2012.

7. Waiving Lugar Redesignation for the Out-Migration Adjustment

We have received several inquiries regarding the effect on a hospital's deemed urban status when a hospital waives its reclassification under section 1886(d)(8) of the Act in order to accept an out-migration adjustment to the wage index under section 1886(d)(13) of the Act. (We refer readers to a discussion of the out-migration adjustment under section III.I. of the preamble of this proposed rule.) In this proposed rule,

we are clarifying that Lugar hospitals will be required to waive their Lugar urban status in its entirety in order to receive the out-migration adjustment. We believe this represents a permissible reading of the statute, as section 1886(d)(13)(G) of the Act states that a hospital with an out-migration adjustment is not "eligible" for a reclassification under subsection (8). Therefore, beginning with FY 2012, we are proposing that an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the DSH payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. (We refer readers to a discussion of DSH payment adjustment under section IV.G. of this preamble.)

In addition, we are proposing to make a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to automatically waive its urban status for the 3-year period for which its out-migration adjustment is effective. That is, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the adjustment. We are making this proposal in response to public comments we received on the FY 2011 IPPS/LTCH proposed rule that discussed the burden of this annual request (74 FR 43840). Thus, under the proposed procedural change, a Lugar hospital that requests to waive its urban status in order to receive the rural wage index in addition to the out-migration adjustment would be deemed to have accepted the out-migration adjustment and agrees to be treated as rural for the duration of its 3-year eligibility period, unless prior to its second or third year of eligibility the hospital explicitly notifies CMS in writing, within 45 days from the publication of the proposed rule, that it instead elects to return to its deemed urban status and no longer wishes to accept the out-migration adjustment.

8. Other Geographic Reclassification Issues

a. Requested Reclassification for Single Hospital MSAs

Section 412.230 of the regulations sets forth criteria for an individual hospital to apply for geographic reclassification to a higher rural or urban wage index area. Specifically, under § 412.230(a)(3)(ii), an individual hospital may be redesignated from an urban area to another urban area, from a rural area to another rural area, or from a rural area to an urban area for the purpose of using the other area's wage index value. Such a hospital must also meet other criteria. One required criterion (under § 412.230(d)(1)(iii)(C) of the regulations) is that the hospital must demonstrate that its own average hourly wage is higher than the average hourly wage of hospitals in the area in which the hospital is located (108 percent for urban hospitals and 106 percent for rural hospitals). In cases where a hospital wishing to reclassify is the only hospital in its MSA, that hospital is unable to satisfy this criterion because it cannot demonstrate that its average hourly wage is higher than that of the other hospitals in the area in which the hospital is located (because there are no other hospitals in the area). For hospitals in the category described above, our current policy provides an alternative that allows hospitals to seek reclassification using the group reclassification rules under § 412.232 or § 412.234. Specifically, if a hospital is the single hospital in its area for the 3-year period over which the average hourly wage is calculated for the purpose of the comparison under § 412.230(d)(1)(iii)(C), the hospital may apply for geographic reclassification as a single hospital county group in accordance with the procedures set forth at § 412.232 or § 412.234. In addition to specifying the average hourly wage criteria, these regulations state that the county in which the hospital is located must be adjacent to the urban area to which it seeks redesignation. In addition, a certain level of economic integration needs to exist between the two areas. For example, for urban county group reclassifications (for FY 2008 and subsequent periods), § 412.234(a)(3)(iv) states that "hospitals located in counties that are in the same Combined Statistical Area (CSA) or Core-Based Statistical Area (CBSA) * * * as the urban area to which they seek redesignation qualify as meeting the proximity requirements for reclassification to the urban area to which they seek redesignation."

Recently, we have been advised of a single hospital MSA scenario of concern to a particular hospital. In this scenario, an urban hospital located in an area in which there was only one other hospital had previously applied for and was granted a reclassification by the MGCRB to an adjacent urban area with a higher wage index. During the 3-year reclassification timeframe, the other hospital in its labor market area closed. After the expiration of its reclassification, the hospital became ineligible for reclassification to that same adjacent urban area with a higher wage index because it was no longer able to satisfy the wage data comparison criteria to reclassify individually under § 412.230(d)(1)(iii)(C). In addition, the hospital could not apply for redesignation under the urban county group regulation at § 412.234 because the hospital was not located in the same CSA or CBSA as the urban area to which it sought reclassification. In this example, the concern that was shared with CMS was that the hospital was competitively disadvantaged in competing for labor with neighboring hospitals where the hospital had a comparable average hourly wage, compared to the other hospitals in its surrounding area, because it receives a lower wage index.

We believe that the geographic reclassification regulations should not be revised to accommodate this situation. We have repeatedly rejected special rules to accommodate single hospital MSAs (69 FR 48915, 49109; 71 FR 47869, 48071 and 48072). In these explanations, we have highlighted the fact that hospitals in single hospital MSAs not only may be eligible for out-commuting adjustments, but that they also may apply to an adjacent MSA within the same CSA using the group reclassification rules without meeting the 108-percent test. Each year, we propose to adopt the OMB's statistical area definitions (75 FR 50162), so if a hospital in a single hospital MSA cannot meet group reclassification criteria because of the CSA standard, it means that OMB has determined that there is not a sufficient degree of employment interchange to suggest that the areas compete for the same labor. In addition, when we originally adopted the 108-percent test, we noted that "with respect to single hospital MSAs, a hospital in such an MSA receives a wage index value that is based entirely on its own wage data and, therefore, its actual wage levels. Since such a hospital is clearly not disadvantaged by its inclusion in a labor market area where its wage index is determined based on

its own wage levels, it is appropriate under this guideline that a hospital should not be reclassified if it is the only one in its area." (57 FR 39746) Allowing a hospital representing 100 percent of its area's wages to be exempt from the wage data comparison test could undermine the 108-percent test for hospitals in other circumstances where the standard cannot be met. Finally, we note that section 3137(c) of the Affordable Care Act prohibits us from altering average hourly wage comparison criteria for FY 2012. That provision states that "notwithstanding any other provision of law," the MGCRB is required to use the "average hourly wage comparison criteria used in making such decisions as of September 30, 2008," until the first fiscal year beginning on the date that is one year after the Secretary submits a report to Congress.

We are soliciting public comments on this issue. In particular, we invite comments on the types of regulatory solutions that could be made available to a hospital in this type of situation.

b. Requests for Exceptions to Geographic Reclassification Rules

Over the last several years, CMS has received numerous requests for exceptions to current Medicare law and regulation regarding geographic reclassification or requests to revise the existing regulations in order to allow a hospital or group of hospitals the ability to reclassify to a labor market area with a higher wage index. Section 3137(b) of the Affordable Care Act requires the Secretary to submit a report to Congress that includes a "plan to reform the hospital wage index." This report to Congress is due by December 31, 2011. As part of our efforts in this regard, we are soliciting public comments, to be considered only as part of our report to Congress and not to be addressed in the FY 2012 IPPS/LTCH PPS final rule, on ways to redefine the geographic reclassification requirements to more accurately define labor markets.

I. Proposed FY 2012 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with the broad discretion granted to the Secretary under section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the "out-migration" adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index. Such adjustments to the wage index are effective for 3 years, unless a hospital requests to waive the application of the adjustment. A county will not lose its status as a qualifying county due to hospital wage index changes during the 3-year period, and counties will receive the same wage index increase for those 3 years. However, a county that qualifies in any given year may not necessarily qualify after the 3-year period, or it may qualify but receive a different adjustment to the wage index level. Hospitals that receive this adjustment to their wage index are not eligible for reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act. Adjustments under this provision are not subject to the budget neutrality requirements under section 1886(d)(3)(E) of the Act.

Hospitals located in counties that qualify for the wage index adjustment are to receive an increase in the wage index that is equal to the average of the differences between the wage indices of the labor market area(s) with higher wage indices and the wage index of the resident county, weighted by the overall percentage of hospital workers residing in the qualifying county who are employed in any labor market area with a higher wage index. Beginning with the FY 2008 wage index, we use post-reclassified wage indices when determining the out-migration adjustment (72 FR 47339).

For the proposed FY 2012 wage index, we are proposing to calculate the out-migration adjustment using the same formula described in the FY 2005 IPPS final rule (69 FR 49064), with the addition of using the post-reclassified wage indices, to calculate the out-migration adjustment. This adjustment is calculated as follows:

Step 1—Subtract the wage index for the qualifying county from the wage index of each of the higher wage area(s) to which hospital workers commute.

Step 2—Divide the number of hospital employees residing in the qualifying county who are employed in such higher wage index area by the total number of hospital employees residing in the qualifying county who are employed in any higher wage index area. For each of the higher wage index areas, multiply this result by the result obtained in Step 1.

Step 3—Sum the products resulting from Step 2 (if the qualifying county has workers commuting to more than one higher wage index area).

Step 4—Multiply the result from Step 3 by the percentage of hospital employees who are residing in the qualifying county and who are employed in any higher wage index area.

These adjustments will be effective for each county for a period of 3 fiscal years. For example, hospitals that received the adjustment for the first time in FY 2011 will be eligible to retain the adjustment for FY 2012. For hospitals in newly qualified counties, adjustments to the wage index are effective for 3 years, beginning with discharges occurring on or after October 1, 2011.

Hospitals receiving the wage index adjustment under section 1886(d)(13)(F) of the Act are not eligible for reclassification under sections 1886(d)(8) or (d)(10) of the Act unless they waive the out-migration adjustment. Consistent with our FYs 2005 through 2011 IPPS final rules, we are specifying that hospitals redesignated under section 1886(d)(8) of the Act or reclassified under section 1886(d)(10) of the Act are deemed to have chosen to retain their redesignation or reclassification. Hospitals that reclassified under section 1886(d)(10) of the Act that wish to receive the out-migration adjustment, rather than their reclassification adjustment, are instructed to follow the termination/withdrawal procedures specified in 42 CFR 412.273 and section III.H.3. of the preamble of this proposed rule. Otherwise, they will be deemed to have waived the out-migration adjustment. Hospitals redesignated under section 1886(d)(8)(B) of the Act will be deemed to have waived the out-migration adjustment unless they explicitly notify CMS within 45 days from the publication of this proposed rule that they elect to receive the out-migration adjustment instead. These notifications should be sent to the following address: Centers for Medicare and Medicaid Services, Center for Medicare, Attention: Wage Index Adjustment Waivers, Division of Acute Care, Room C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Table 4J, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, lists the proposed out-migration wage index adjustments for FY 2012. Hospitals that are not otherwise reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act will automatically receive the listed adjustment. In accordance with the procedures discussed above, redesignated/reclassified hospitals will be deemed to have waived the out-

migration adjustment unless CMS is otherwise notified within the timeframe stated above. In addition, hospitals eligible to receive the out-migration wage index adjustment and that withdraw their application for reclassification will automatically receive the wage index adjustment listed in Table 4J, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet.

J. Process for Requests for Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data and occupational mix survey data files for the proposed FY 2012 wage index were made available on October 4 2010, through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional public use file on our Web site that reflects the actual data that are used in computing the proposed wage index. The release of this new file does not alter the current wage index process or schedule. We notified the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door forum. We encouraged hospitals to sign up for automatic notifications of information about hospital issues and the scheduling of the Hospital Open Door forums at: *http://www.cms.hhs.gov/OpenDoorForums/.*

In a memorandum dated October 13, 2010, we instructed all fiscal intermediaries/MACs to inform the IPPS hospitals they service of the availability of the wage index data files and the process and timeframe for requesting revisions (including the specific deadlines listed below). We also instructed the fiscal intermediaries/MACs to advise hospitals that these data were also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in the October 4, 2010 wage and occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its fiscal intermediary/MAC by December 6, 2010. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted on the preliminary wage index data files on the Internet, through the October 13, 2010 memorandum referenced above.

In the October 13, 2010 memorandum, we also specified that a hospital requesting revisions to its occupational mix survey data was to copy its record(s) from the CY 2007–2008 occupational mix preliminary files posted to our Web site in October, highlight the revised cells on its spreadsheet, and submit its spreadsheet(s) and complete documentation to its fiscal intermediary/MAC no later than December 6, 2010.

The fiscal intermediaries/MACs notified the hospitals by mid-February 2011 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' early-December revision requests. The fiscal intermediaries/MACs also submitted the revised data to CMS by mid-February 2011. CMS published the proposed wage index public use files that included hospitals' revised wage index data on February 22, 2011. Hospitals had until March 7, 2011, to submit requests to the fiscal intermediaries/MACs for reconsideration of adjustments made by the fiscal intermediaries/MACs as a result of the desk review, and to correct errors due to CMS's or the fiscal intermediary's (or, if applicable, the MAC's) mishandling of the wage index data. Hospitals also were required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, fiscal intermediaries/MACs are required to transmit any additional revisions resulting from the hospitals' reconsideration requests by April 13, 2011. The deadline for a hospital to request CMS intervention in cases where the hospital disagrees with the fiscal intermediary's (or, if applicable, the MAC's) policy interpretations is April 20, 2011.

Hospitals should examine Table 2, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet. Table 2 contains each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2008 data used to construct the proposed FY 2012 wage index. We note that the hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data and transmitted to CMS by March 2011.

We will release the final wage index data public use files in early May 2011 on the Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp.* The May 2011 public use files are made available solely for the limited purpose of identifying any potential errors made by CMS or the fiscal intermediary/MAC in the entry of the final wage index data that resulted from the correction process described above (revisions submitted to CMS by the fiscal intermediaries/MACs by April 13, 2011). If, after reviewing the May 2011 final files, a hospital believes that its wage or occupational mix data are incorrect due to a fiscal intermediary/MAC or CMS error in the entry or tabulation of the final data, the hospital should send a letter to both its fiscal intermediary/MAC and CMS that outlines why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). CMS and the fiscal intermediaries (or, if applicable, the MACs) must receive these requests no later than June 6, 2011.

Each request also must be sent to the fiscal intermediary/MAC. The fiscal intermediary/MAC will review requests upon receipt and contact CMS immediately to discuss any findings.

At this point in the process, that is, after the release of the May 2011 wage index data files, changes to the wage and occupational mix data will only be made in those very limited situations involving an error by the fiscal intermediary/MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the fiscal intermediary/MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by fiscal intermediaries or the MACs on or before April 13, 2011.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 22, 2011 wage index public use files.
- Requests to revisit factual determinations or policy interpretations made by the fiscal intermediary or the MAC or CMS during the wage index data correction process.

Verified corrections to the wage index data received timely by CMS and the fiscal intermediaries or the MACs (that is, by June 6, 2011) will be incorporated into the final wage index in the FY 2012 IPPS/LTCH PPS final rule, which will be effective October 1, 2011.

We created the processes described above to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2012 payment rates. Accordingly, hospitals that do not meet

the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the fiscal intermediary's (or, if applicable, the MAC's) decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the Provider Reimbursement Review Board, the failure of CMS to make a requested data revision. (See *W. A. Foote Memorial Hospital* v. *Shalala,* No. 99–CV–75202–DT (E.D. Mich. 2001) and *Palisades General Hospital* v. *Thompson,* No. 99–1230 (D.D.C. 2003).) We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appealing to the PRRB for wage index data corrections.

Again, we believe the wage index data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the fiscal intermediary's (or, if applicable, the MAC's) attention. Moreover, because hospitals have access to the final wage index data by early May 2011, they have the opportunity to detect any data entry or tabulation errors made by the fiscal intermediary or the MAC or CMS before the development and publication of the final FY 2012 wage index by August 2011, and the implementation of the FY 2012 wage index on October 1, 2011. If hospitals avail themselves of the opportunities afforded to provide and make corrections to the wage and occupational mix data, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after June 6, 2011, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our existing regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The fiscal intermediary or the MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, "before the beginning of the fiscal year" means by the June 6 deadline for making corrections to the wage data for the following fiscal year's wage index. This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS Web site prior to publishing both the proposed and final IPPS rules, and the fiscal intermediaries or the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when: (1) The fiscal intermediary (or, if applicable, the MAC) or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the fiscal intermediary (or, if applicable, the MAC) and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the June 6, 2011 deadline for the FY 2012 wage index); and (3) CMS agreed that the fiscal intermediary (or, if applicable, the MAC) or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the June 6, 2011 deadline), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the fiscal intermediary's (or, if applicable, the MAC's) mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In other situations where our policies would allow midyear corrections, we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a judicial decision reverses a CMS denial of a hospital's wage index data revision request.

K. Labor-Related Share for the Proposed FY 2012 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related: "The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates * * *" We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this "would result in lower payments to a hospital than would otherwise be made." However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate "from time to time" the proportion of hospitals' costs that are "attributable to wages and wage-related costs." We believe that this reflected Congressional intent that hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43850 through 43856), we rebased and revised the hospital market basket for operating costs. We established a FY–2006-based IPPS hospital market basket to replace the FY as 2002-based IPPS hospital market basket, effective October 1, 2009. In that final rule, we presented our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY as 2010. We also recalculated a labor-related share of 68.8 percent, using the FY 2006-based IPPS market basket, for

discharges occurring on or after October 1, 2009. In addition, we implemented this revised and rebased labor-related share in a budget neutral manner, but consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. In this proposed rule, we are not proposing to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, fringe benefits, contract labor, the labor-related portion of professional fees, administrative and business support services, and all other labor-related services (previously referred to in the FY 2002-based IPPS market basket as labor-intensive).

Therefore, for FY 2012, we are proposing to continue to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2011. Tables 1A and 1B, which are published in section VI. of the Addendum to this proposed rule and available via the Internet, reflect this labor-related share. We note that section 403 of Public Law 108–173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this employment "would result in lower payments to a hospital than would otherwise be made." Therefore, for all IPPS hospitals whose wage indices are less than 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals whose wage indices are greater than 1.0000, we are proposing to apply the wage index to a labor-related share of 68.8 percent of the national standardized amount.

For Puerto Rico hospitals, the national labor-related share will always be 62 percent because the national wage index for all Puerto Rico hospitals is less than 1.0. In this proposed rule, we are proposing to continue to use a labor-related share for the Puerto Rico-specific standardized amounts of 62.1 percent for discharges occurring on or after October 1, 2011. This Puerto Rico labor-related share of 62.1 percent was also adopted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43857) at the time the FY 2006-based hospital market basket was established, effective October 1, 2009. Consistent with our methodology for determining the national labor-related share, we added the Puerto Rico-specific relative weights for wages and salaries, fringe benefits, contract labor, the labor-related portion of professional fees, administrative and business support services, and all other labor-related services (previously referred to in the FY 2002-based IPPS market basket as labor-intensive) to determine the labor-related share. Puerto Rico hospitals are paid based on 75 percent of the national standardized amounts and 25 percent of the Puerto Rico-specific standardized amounts. The labor-related share of a hospital's Puerto Rico-specific rate will be either the Puerto Rico-specific labor-related share of 62.1 percent or 62 percent, depending on which results in higher payments to the hospital. If the hospital has a Puerto Rico-specific wage index of greater than 1.0, we will set the hospital's rates using a labor-related share of 62.1 percent for the 25 percent portion of the hospital's payment determined by the Puerto Rico standardized amounts because this amount will result in higher payments. Conversely, a hospital with a Puerto Rico-specific wage index of less than 1.0 will be paid using the Puerto Rico-specific labor-related share of 62 percent of the Puerto Rico-specific rates because the lower labor-related share will result in higher payments. The Puerto Rico labor-related share of 62.1 percent for FY 2012 is reflected in Table 1C, which is published in section VI. of the Addendum to this proposed rule and available via the Internet.

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

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. Overview

CMS is seeking to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of an increasing number of widely-agreed upon quality measures. CMS has worked with relevant stakeholders to define measures of quality in almost every setting and measures various aspects of care for almost all Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and, increasingly, outcomes.

CMS has implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, CMS implemented the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). In addition, CMS has implemented quality reporting programs for hospital outpatient services, the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), and for physicians and other eligible professionals, the Physician Quality Reporting System (formerly referred to as the Physician Quality Reporting Program Initiative (PQRI)). CMS has also implemented quality reporting programs for home health agencies and skilled nursing facilities that are based on conditions of participation, and an end-stage renal disease quality incentive program that links payment to performance.

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal for the future is to align the clinical quality measure requirements of the Hospital IQR Program with various other programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act so that the burden for reporting will be reduced.

We also are proposing to implement a Hospital Value-Based Purchasing (VBP) Program under section 1886(o) of the Act. On January 7, 2011, we issued a proposed rule to implement the Hospital VBP Program under section 1886(o) of the Act (76 FR 2454 through 2491) (the Hospital Inpatient VBP Program proposed rule). We are proposing additional policies for the Hospital VBP Program in section IV.B. of this proposed rule. In the Hospital Inpatient VBP Program proposed rule (76 FR 2454 through 2491), we proposed that hospitals would receive value-based incentive payments if they meet performance standards with respect to measures for a performance period for the fiscal year involved. The measures under the Hospital VBP Program must be selected from the measures specified under the Hospital IQR Program. The Hospital VBP Program will apply to payments for discharges occurring on or after October 1, 2012, in accordance with section 1886(o) of the Act.

The Hospital IQR Program is intertwined with the Hospital VBP Program because the measures and reporting infrastructure for both programs will overlap. We view the

Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare into an active purchaser of quality health care for its beneficiaries. As we stated in the Hospital Inpatient VBP Program proposed rule (76 FR 2455), in developing that proposed rule as well as other value-based payment initiatives, we applied the following principles for the development and use of measures and scoring methodologies:

Purpose:

• We view value-based purchasing as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume.

Use of Measures:

• Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.

• To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.

• The collection of information should minimize the burden on providers to the extent possible. As part of that effort, we will continuously seek to align our measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.

• To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We invite public comment on these principles.

b. Statutory History and History of Measures Adopted for the Hospital IQR Program

We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43860) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180) for detailed discussions of the history of the Hospital IQR Program, including the statutory history and the measures we have adopted for the Hospital IQR measure set through FY 2014.

Section 1886(b)(3)(B)(viii)(V) of the Act requires that, effective for payments beginning with FY 2008, the Secretary to add quality measures that reflect consensus among affected parties, and to the extent feasible and practicable, have been set forth by one or more national consensus building entities. We are seeking comments on an option that would allow us from time to time to consider a range of consensus endorsement entities or bodies that can assist us with our measure development process. We believe that this approach would provide for a diverse endorsement process and the best body of evidence to support quality measures used in our quality programs.

c. Maintenance of Technical Specifications for Quality Measures

The technical specifications for the Hospital IQR Program measures, or links to Web sites hosting technical specifications, are contained in the CMS/The Joint Commission Specifications Manual for National Hospital Inpatient Quality Measures (Specifications Manual). This Specifications Manual is posted on the CMS QualityNet Web site at *https://www.QualityNet.org*. We maintain the technical specifications by updating this Specifications Manual semiannually, or more frequently in unusual cases, and include detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. These semiannual updates are accompanied by notifications to users, providing sufficient time between the change and the effective date in order to allow users to incorporate changes and updates to the specifications into data collection systems.

The technical specifications for the HCAHPS patient experience of care survey are contained in the current HCAHPS *Quality Assurance Guidelines* manual, which is available at the HCAHPS On-Line Web site, *http://www.hcahpsonline.org*. We maintain the HCAHPS technical specifications by updating the HCAHPS *Quality Assurance Guidelines* manual annually, and include detailed instructions on survey implementation, data collection, data submission and other relevant topics. As necessary, HCAHPS Bulletins are issued to provide notice of changes and updates to technical specifications in HCAHPS data collection systems.

d. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, requires that the Secretary establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. We are proposing to display information regarding the measures (such as names of measures for which data will be displayed in the future) on the *Hospital Compare* Web site under this provision, and invite public comment on this proposal. We will continue our current practice of reporting data from the Hospital IQR Program as soon as it is feasible on CMS Web sites such as the *Hospital Compare* Web site, *http://www.hospitalcompare.hhs.gov* after a 30-day preview period.

The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. It further serves to encourage beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they furnish. The Hospital IQR Program currently includes process of care measures, risk-adjusted outcome measures, the HCAHPS patient experience-of-care survey, and structural measures, all of which are featured on the *Hospital Compare* Web site.

However, information that may not be relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations for inclusion on *Hospital Compare* may be made available on other CMS Web sites that are not intended to be used as an interactive Web tool, such as *http://www.cms.hhs.gov/HospitalQualityInits/*. Publicly reporting the information in this manner, though not on the *Hospital Compare* Web site, allows CMS to meet the requirement under section 1886(b)(3)(B)(viii)(VII) of the Act for establishing procedures to make information regarding measures submitted under the Hospital IQR Program available to the public

following a preview period. In such circumstances, affected parties are notified via CMS listservs, CMS e-mail blasts, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare*.

2. Retirement of Hospital IQR Program Measures

a. Considerations in Retiring Quality Measures From the Hospital IQR Program

We generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets. We previously retired one "topped out" measure, PN–1: Oxygenation Assessment for Pneumonia, from the Hospital IQR Program on the basis of high unvarying performance among hospitals, because measures with very high performance among hospitals present little opportunity for improvement, and do not provide meaningful distinctions in performance for consumers.

We also have retired one measure from the Hospital IQR Program because it no longer "represent[ed] the best clinical practice," as required under section 1886(b)(3)(B)(viii)(VI) of the Act. We stated that when there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns, we believe that it is appropriate for CMS to take immediate action to remove a measure from the Hospital IQR Program and not wait for the annual rulemaking cycle. Therefore, we adopted the policy (74 FR 43864 and 43865) that we would promptly retire such a measure, confirm the retirement in the next IPPS rulemaking cycle, and notify hospitals and the public of the decision to promptly retire measures through the usual hospital and QIO communication channels used for the Hospital IQR Program. These channels include memos and e-mail notification and QualityNet Web site articles and postings.

As we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), among the criteria that we consider when determining whether to retire Hospital IQR Program measures are the following: (1) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made; (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; (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. These criteria were suggested by commenters during rulemaking, and we agreed that these criteria should be among those considered in evaluating Hospital IQR Program measures for retirement.

b. Proposed Retirement of Hospital IQR Program Measures for the FY 2014 Payment Determination and Subsequent Years

In order to reduce the reporting burden on hospitals, and in particular, the burden associated with reporting chart-abstracted measures, we have considered options to accommodate the expansion of the measure set through the retirement of additional Hospital IQR measures. Specifically, we have considered retiring one or more of the measures suggested by various commenters that were listed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43865). We noted in that final rule that commenters recommended for retirement 11 Hospital IQR Program chart-abstracted measures. Seven of these 11 measures were recommended by commenters for retirement based on their performance being uniformly high nationwide, with little variability among hospitals (topped-out measures). Based on our own analysis, we concluded that these measures are topped out and for this reason, we proposed not to include them in the FY 2013 Hospital VBP Program measure set (76 FR 2460). These measures are listed below:

- AMI–1 Aspirin at arrival
- AMI–3 ACEI/ARB for left ventricular systolic dysfunction
- AMI–4 Adult smoking cessation advice/counseling
- AMI–5 Beta-blocker prescribed at discharge
- HF–4 Adult smoking cessation advice/counseling
- PN–4 Adult smoking cessation advice/counseling
- SCIP INF–6 Appropriate Hair Removal

The methodology we used to determine that these measures are topped out is detailed in the Hospital Inpatient VBP Program proposed rule (76 FR 2460). We are proposing to retire these topped out measures from the Hospital IQR measure set. In addition, we proposed to not include an eighth measure in the FY 2013 Hospital VBP Program measure set because we believe that inclusion of this measure would result in the unintended consequence of inappropriate antibiotic use (76 FR 2462). This measure is PN–5c Timing of receipt of initial antibiotic following hospital arrival. We are also proposing to retire this measure from the Hospital IQR Program because of the potential for this negative unintended consequence.

For these reasons, we are proposing to retire these eight measures from the Hospital IQR measure set for FY 2014 and subsequent years, and that hospitals would no longer be required to submit data on these measures starting with January 1, 2012 discharges. We invite public comment on this proposal.

3. Proposed Measures for the FY 2014 and FY 2015 Hospital IQR Payment Determinations

a. Considerations in Expanding and Updating Quality Measures Under the Hospital IQR Program

In general, we seek to adopt measures for the Hospital IQR Program that promote better, safer, more efficient care. Our measure development and selection activities for the Hospital IQR Program take into account national priorities, such as those established by the National Priorities Partnership, HHS Strategic Plan, the National Strategy for Quality Improvement in Healthcare, as well as other widely accepted criteria established in medical literature. (We refer readers to the following Web sites regarding these priorities: *http://www.nationalprioritiespartnership.org/* (National Priorities Partnership); *http://www.hhs.gov/secretary/about/priorities/priorities.html* (HHS Strategic Plan); and *http://www.healthcare.gov/center/reports/quality03212011a.html* (National Strategy for Quality Improvement in Healthcare)). To the extent practicable, we have sought to adopt measures which have been endorsed by a national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers and other stakeholders. Because measures for the Hospital VBP Program must be selected from the measures specified for the Hospital IQR Program, the measures to be selected for inclusion in the Hospital VBP Program also reflect these priorities. In addition, we believe it is important to expand the pool of measures to include measures that are directed toward improving patient

safety. This goal is supported by at least two Federal reports documenting that tens of thousands of patients do not receive safe care in the nation's hospitals.[6] [7]

Section 3001(a)(2) of the Affordable Care Act amended the Act by adding a new section 1886(b)(3)(B)(viii)(VIII) of the Act. This section states that, "[e]ffective for payments beginning with fiscal year 2013, with respect to quality measures for outcomes of care, the Secretary shall provide for such risk adjustment as the Secretary determines to be appropriate to maintain incentives for hospitals to treat patients with severe illnesses or conditions." Section 3001(a)(2) of the Affordable Care Act also added new sections 1886(b)(3)(B)(viii)(IX)(aa) and (bb) of the Act. These sections state that "* * * effective for payments beginning with fiscal year 2013, each measure specified by the Secretary under this clause shall be endorsed by the entity with a contract under section 1890(a) [of the Act]," and "[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary." In the FY 2011 IPPS/LTCH PPS final rule, we established that all of the measures adopted in that rule for the FY 2013 and FY 2014 payment determinations meet these standards (75 FR 50200).

We have previously acknowledged the data collection burden for hospitals participating in the Hospital IQR Program, and reiterated our desire to expand the Hospital IQR Program measure set while minimizing burden and seeking to provide alternative mechanisms for data submission (75 FR 50189). We also stated that in future expansions and updates to the Hospital IQR Program measure set, we would be taking into consideration several important goals. These goals include: (a) Expanding the types of measures beyond process of care measures to include an increased number of outcome measures, efficiency measures, and patients' experience-of-care measures; (b) expanding the scope of hospital services to which the measures apply; (c) considering the burden on hospitals in collecting chart-abstracted data; (d) harmonizing the measures used in the Hospital IQR Program with other CMS quality programs to align incentives and promote coordinated efforts to improve quality; (e) seeking to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims databases; and, (f) weighing the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital IQR Program.

Specifically, we give priority to measures that assess performance on: (a) Conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and, (c) conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. We have used and continue to use these criteria to guide our decisions regarding what measures to add to the Hospital IQR Program measure set. In addition, in selecting measures, we seek to address the six quality aims of effective, safe, timely, efficient, patient-centered, and equitable healthcare. Current and long term priority topics include: Prevention and population health; safety; chronic conditions; high cost and high volume conditions; elimination of health disparities; healthcare-associated infections (HAIs) and other adverse healthcare outcomes; improved care coordination; improved efficiency; improved patient and family experience of care; effective management of acute and chronic episodes of care; reduced unwarranted geographic variation in quality and efficiency; and adoption and use of interoperable HIT.

Hospital IQR Program measures were initially based solely on a hospital's submission of chart-abstracted quality measure data. However, in recent years we have adopted measures that do not require chart abstraction, including structural measures and claims-based measures that we can calculate using other data sources. This approach supports our goal of expanding the measures for the Hospital IQR Program while minimizing the burden on hospitals and, in particular, without significantly increasing the chart abstraction burden.

In addition to structural measures and claims-based measures, we previously noted that registries are potential alternative sources of hospital data for the Hospital IQR Program. (A registry is a collection of clinical data for purposes of assessing clinical performance, quality of care, and opportunities for quality improvement.) We envisioned that instead of requiring hospitals to submit the same data to CMS that many hospitals are already submitting to registries, we would collect the data directly from the registries. This could enable the expansion of the Hospital IQR Program measure set without increasing the burden of data collection for those hospitals participating in the registries. We have previously adopted structural measures of registry participation, and we continue to evaluate the feasibility of leveraging registry-based data collection mechanisms for the Hospital IQR Program.

We also stated our intention to explore mechanisms for data submission using electronic health records (EHRs) (73 FR 48614; 74 FR 43866, 43892; and 75 FR 50189). Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, the adoption of measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and burden to hospitals. We believe that automatic collection and reporting of data through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and that at a future date, such as FY 2015, hospitals will be able to switch solely to EHR-based reporting of data that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We reiterate our commitment to pursue our goals to expand and update quality measures under the Hospital IQR Program and also to minimize burden. We note that in addition to the input we described above, we take into consideration the measures adopted by the Hospital Quality Alliance (HQA) as well as an array of input from the public. The HQA is a national public-private collaboration that is committed to making meaningful, relevant, and easily understood information about hospital performance accessible to the public and to informing and encouraging efforts to improve quality. We appreciate HQA's integral efforts to

[6] OEI–06–09–00090, "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries." Department of Health and Human Services, Office of Inspector General, November 2010.

[7] 2009 National Healthcare Quality Report, pp. 107–122. "Patient Safety," Agency for Healthcare Research and Quality.

improve hospital quality of care and its support of our public quality reporting programs.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50191 through 502192), we finalized our proposal to adopt measures for the Hospital IQR Program for three consecutive payment determinations. The intent of this policy was to provide greater certainty for hospitals to plan to meet future reporting requirements and implement related quality improvement efforts. Aside from giving hospitals more advance notice in planning quality reporting, this 3-year approach also provides more time for us to prepare, organize and implement the infrastructure needed to collect data on the measures and make payment determinations. We indicated, however, that these preliminary measure sets could still be updated through the rulemaking process should we need to respond to agency and/or legislative changes.

Finally, in section IV.A.5.a.(2) of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50219 through 50220), we adopted a proposal to make Hospital IQR Program payment determinations beginning with FY 2013 using one calendar year of data for chart-abstracted measures. We will use this approach, which synchronizes the quarters for which data on these measures must be submitted during each year with the quarters used to make payment determinations with respect to a fiscal year beginning with January 1, 2011 discharges. However, it will not affect our payment determinations until FY 2013.

Section 1886(o)(2)(A) of the Act requires the Secretary to select measures, other than readmission measures, for the Hospital VBP Program from the measures specified under the Hospital IQR Program. Section 1886(o)(2)(B)(i)(I) of the Act states that, for FY 2013, the selected measures must cover at least the following five specified conditions or procedures: Acute myocardial infarction (AMI), Heart failure (HF), Pneumonia (PN), Surgeries, as measured by the Surgical Care Improvement Project (SCIP), and Healthcare-associated infections (HAIs), as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections (or any successor plan) of the Department of Health and Human Services. Section 1886(o)(2)(B)(i)(II) of the Act provides that, for FY 2013, measures selected for the Hospital Inpatient Program must also be related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS).

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework of the Hospital VBP Program. We will focus on selecting measures that we believe will also meet the Hospital VBP Program measure inclusion criteria and advance the goals of the Hospital VBP Program by targeting hospitals' ability to improve patient care and patient outcomes.

In addition, in order to support HHS priorities such as patient safety and reduction of HAIs and readmissions, and meet more of the widespread goals of the Affordable Care Act in terms of improving the quality of care provided to Medicare beneficiaries, we are proposing in this proposed rule to adopt measures for the FY 2014 and FY 2015 Hospital IQR payment determinations. However, we note that the final measure sets to be used for these years' payment determinations could be changed via future rulemaking. This allows CMS the flexibility to accommodate changes in program needs and legislative changes. We invite public comment on these proposals.

b. Proposed Hospital IQR Program Measures for the FY 2014 Hospital IQR Payment Determination

(1) Proposed Retention of 52 Hospital IQR Program Measures Finalized in the FY 2011 IPPS/LTCH PPS Final Rule for the FY 2014 Payment Determination

We previously finalized 60 measures for the FY 2014 Hospital IQR Program measure set. However, as we discussed above, we are proposing to retire 8 measures from the FY 2014 measure set. We are proposing to retain the remaining 52 the 60 quality measures finalized in the FY 2011 IPPS/LTCH PPS final rule for the FY 2014 payment determination. We invite public comment on our proposal to retain 52 quality measures for the FY 2014 payment determination.

(2) Proposed Additional Hospital IQR Program Measures for the FY 2014 Payment Determination

(A) Proposed CDC/NHSN-Based Healthcare-Associated Infection (HAI) Measures

HAIs are among the leading causes of death in the U.S. The Centers for Disease Control (CDC) estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths per year.[8] It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs.

HAIs are largely preventable with widely publicized interventions such as better hygiene and advanced scientifically tested techniques for surgical patients. Therefore, the public reporting of HAIs has been of great interest to many health care consumers and advocacy organizations because it promotes awareness and permits health care consumers to choose the hospitals with lower HAI rates, as well as gives hospitals an incentive to improve infection control efforts. To maximize the efficiency and improve the coordination of HAI prevention efforts across the Department, HHS established in 2008 a senior-level Steering Committee for the Prevention of Healthcare-Associated Infections. In 2009, the Steering Committee, along with scientists and program officials across the government, developed the HHS Action Plan to Prevent Healthcare-Associated Infections, providing a roadmap for HAI prevention in acute care hospitals. In the first iteration of the Action Plan, the Steering Committee chose to focus on infections in acute care hospitals because the associated morbidity and mortality was most severe in that setting and the scientific information on prevention and the capacity to measure improvement was most complete. Thus, prevention of HAIs in acute care hospitals became the first phase of the Action Plan and it focuses on six high priority HAI-related areas.

In addition, the Steering Committee included in the Action Plan five-year goals for nine specific measures of improvement tied to the six HAI prevention priority areas. Since the release of the first Action Plan in June 2009, the Steering Committee has been developing a successor plan in collaboration with public and private partners which is expected to incorporate advances in science and technology and expand the scope to the outpatient environment. The successor plan is also expected to address the health and safety of healthcare personnel, as well as the risks of influenza transmission from healthcare personnel to patients. The second Action Plan is due for publication in 2011.

We also note that the House Committee on Appropriations asked in a 2009 Report that CMS include in its "pay for reporting" system two infection control measures developed by the

[8] McKibben L, Horan T. Guidance on public reporting of healthcare-associated infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005; 33:217–26

Hospital Quality Alliance (HQA)—Central line-associated bloodstream infections and a surgical site infection rate (H. Rep. No. 111–220, at 159 (2009)). In the report, the Committee stated that "if the measures are included in *Hospital Compare,* the public reporting of the data is likely to reduce HAI occurrence, an outcome demonstrated in previous research."

In the FY 2011 IPPS/LTCH PPS final rule, we adopted the two HAI measures identified by the House Committee on Appropriations in its 2009 report: Central Line [catheter] Associated Blood Stream Infection (CLABSI) measure, and Surgical Site Infection (SSI) measure. The CLABSI measure is currently part of the FY 2013 Hospital IQR measure set, and data submission on the measure began with January 2011 events.[9] The Surgical Site Infection (SSI) measure is currently part of the FY 2014 Hospital IQR measure set, and data submission on the measure will begin with January 2012 events.

In this proposed rule, we are proposing to adopt two additional HAI measures for the FY 2014 Hospital IQR measure set. These proposed measures were developed by the CDC and are currently collected by the CDC via the NHSN. These measures are: (1) Central Line Bundle Compliance (NQF #0298) (referred to by the CDC and in this proposed rule as Central Line Insertion Practices, or CLIP); and (2) Catheter Associated Urinary Tract Infection (CAUTI) (NQF #138). Both measures are high priority HAI measures that are included among the prevention metrics established in the HHS Action Plan to Prevent HAIs which, as we noted above, underscores the importance of reducing HAIs. As detailed below, both measures also meet Hospital IQR Program statutory requirements for measure selection. Furthermore, both measures are currently collected by the NHSN, which is a secure, Internet-based surveillance system maintained and managed by the CDC, and can be utilized by all types of healthcare facilities in the U.S., including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and long term care facilities. The NHSN enables healthcare facilities to collect and use data about HAIs, adherence to clinical practices known to prevent HAIs, the incidence or prevalence of multidrug-resistant organisms within their organizations, and other adverse events. Some States use NHSN as a means for healthcare facilities to submit patient-level data on the measures mandated through their specific State legislation. Currently, 28 States require hospitals to report HAIs using NHSN, and CDC provides support to more than 4,000 hospitals that are using NHSN. NHSN data collection occurs via a Web-based tool hosted by CDC provided free of charge to providers. In addition, data submission for HAI measures through EHRs may be possible in the near future.

(i) Central Line Insertion Practice Adherence Percentage (CLIP)

Central line associated blood stream infections (CLABSIs) can be prevented through proper management of the central line. The CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) *Guidelines for the Prevention of Intravascular Catheter-Related Infections* recommends evidence-based central line insertion practices known to reduce the risk of subsequent central line-associated bloodstream infection.[10] These include hand-washing by inserters, use of maximal sterile barriers during insertion, proper use of a skin antiseptic prior to insertion, and allowing that skin antiseptic to dry before catheter insertion. Despite the scientific evidence supporting these practices, several reports suggest that adherence to these practices remains low in United States hospitals. The proposed CLIP process measure is a companion measure to the previously adopted CLABSI measure, and it assesses the extent to which a facility employs practices consistent with CDC/HICPAC recommendations that are known to reduce CLABSI. There are 2 States that currently require facilities to report to NHSN at least one month of CLIP data.

The CLIP measure is used in State reporting initiatives and is an NQF-endorsed measure (NQF #298) that is operationalized for collection via the NHSN. Therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. This CLIP prevention metric is also listed in the HHS Action Plan to Prevent HAIs and, as we detailed above, has been widely identified as a high priority for public reporting.

(ii) Catheter Associated Urinary Tract Infection (CAUTI)

The urinary tract is the most common site of HAI, accounting for more than 30 percent of infections reported by acute care hospitals.[11] Healthcare-associated urinary tract infections (UTIs) are commonly attributed to catheterization of the urinary tract. CAUTI can lead to such complications as cystitis, pyelonephritis, gram-negative bacteremia, prostatitis, epididymitis, and orchitis in males and, less commonly, endocarditis, vertebral osteomyelitis, septic arthritis, endophthalmitis, and meningitis in all patients. Complications associated with CAUTI cause discomfort to the patient, prolonged hospital stay, and increased cost and mortality. Each year, more than 13,000 deaths are associated with UTIs.[12] Prevention of CAUTIs is discussed in the CDC/HICPAC document, *Guideline for Prevention of Catheter-associated Urinary Tract Infections.* The NQF-endorsed CAUTI measure we are proposing is currently collected by the NHSN as part of State-mandated reporting and surveillance requirements for hospitals. There are 3 States that require facilities to report to NHSN at least one month of CAUTI data.

Section 1886(b)(3)(B)(viii)(IX)(aa) of the Act requires that effective for payments beginning with FY 2013, each measure specified by the Secretary for inclusion in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless the exception set forth in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies. The NQF currently holds the contract under section 1890(a) of the Act, and the NQF has endorsed this CAUTI measure (NQF #138). For this reason, we believe that this measure satisfies the endorsement requirement applicable to the Hospital IQR Program. This proposed measure is currently risk stratified,and therefore is consistent with section 1886(b)(3)(B)(viii)(VIII) of the Act. Risk stratification means that it is calculated using different categories of patients with varying risk of developing an infection. At the time of this proposed rule, this CAUTI measure (NQF #138) is undergoing measure maintenance review by the NQF and we note that the review may result in changes to the specifications. We invite

[9] The CDC captures HAI data based on the onset of an event, rather than based on the discharge date.

[10] O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, *et al.,* Guidelines for the prevention of intravascular catheter-related infections. MMWR 2002;51(No. RR–10:1–26).

[11] Klevens RM, Edward JR, *et al.,* Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160–166.

[12] Wong ES., Guideline for prevention of catheter-associated urinary tract infections. Infect Control 1981;2:126–30.

public comment on our proposal to adopt these two HAI measures into the Hospital IQR Program for the FY 2014 payment determination. We are proposing that hospitals would begin submitting data on these measures beginning with events that occur on or after January 1, 2012. We are also proposing that hospitals use the NHSN infrastructure and protocols, as well as the specifications (available at *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf*) to report the measures for Hospital IQR Program purposes. The proposed reporting mechanism for these HAI measures is discussed in greater detail in section IV.A.5.i. of this proposed rule.

(B) Proposed New Claims-Based Measure

We are proposing to add the following new claim-based measure to the Hospital IQR Program measure set for the FY 2014 payment determination: Medicare Spending per Beneficiary. The details of this measure are discussed below.

(i) Medicare Spending per Beneficiary Measure

Healthcare costs consume an ever-increasing amount of our Nation's resources, straining family, business, and government budgets. Healthcare costs take up a growing share of Federal and State budgets and imperil the governments' long-term fiscal outlooks. In the U.S., the sources of inefficiency that are leading to rising healthcare costs include payment systems that reward medical inputs rather than outcomes. Medicare is transforming from a system that rewards volume of service to one that rewards efficient, effective care and reduces delivery system fragmentation.

In order to further this transformation and help address the critical issue of health care costs, we are proposing to add a measure of Medicare spending per beneficiary to the Hospital IQR Program measure set for the FY 2014 payment determination. This proposed Medicare spending per beneficiary measure addressing the cost of care is a type of measure that is not currently included in the Hospital IQR Program. We are not aware that the NQF or any other consensus organizations under section 1886(b)(3)(B)(viii)(IX) of the Act have currently endorsed any Medicare spending per beneficiary measures. We will give due consideration under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act to any Medicare spending per beneficiary measures that become endorsed in the future. It is important that the cost of care be explicitly measured so that, in conjunction with other measures that we have adopted and are proposing to adopt for the Hospital IQR Program, we can recognize hospitals that are involved in the provision of high quality care at lower cost.

We are proposing that this Medicare spending per beneficiary measure would be calculated using claims data for hospital discharges occurring between May 15, 2012 and February 14, 2013. Therefore, the addition of this proposed measure would not increase the data submission burden on hospitals. We outline below the methodology that we are proposing to use to calculate the measure, if finalized.

• The Medicare Spending per Beneficiary Episode

In order to calculate the Medicare spending per beneficiary for each hospital, we believed that it would be necessary to determine: (1) The timeframe, or length of the "spending per beneficiary episode" during which Medicare payments would be aggregated; (2) the types of Medicare payments to be aggregated over this timeframe; and (3) how to adjust or standardize these payments across hospitals (for example, risk adjustment).

• Length of the Medicare Spending per Beneficiary Episode

We are proposing an episode that runs from three days prior to an inpatient PPS hospital admission (the index admission) through 90 days post hospital discharge. We are proposing to include the time period 90 days post hospital discharge in order to emphasize the importance of care transitions and care coordination in improving patient care. We believe inclusion of this time period surrounding the hospital admission would reinforce the need to reduce adverse outcomes, including readmissions. Encouraging delivery of coordinated care in an efficient manner is an important goal which can best be achieved through inclusion of Medicare payments made outside the timeframe of the hospital inpatient stay.

We recognize that some outcome measures are based on an episode that runs 30 days post discharge. We considered proposing 30 days as the post discharge time period for the episode. However, we believe this shorter time period does not place sufficient emphasis on longer term care transitions and care coordination. Nevertheless, while we are proposing a 90 day post discharge period, we seek public comment on an alternative 30 day time period for the initial implementation of this measure that would be more consistent with the 30 day time period currently in use for some outcome measures.

• Medicare Payments Included in the Spending per Beneficiary Episode

In order to calculate the Medicare spending per beneficiary, it is necessary to define the Medicare payments included in the spending per beneficiary episode. Subject to the adjustments described below, we are proposing to include all Medicare Part A and Part B payments made for services provided to the beneficiary during the episode, including payments made by beneficiaries that we can determine using our claims data, such as Part B deductibles and coinsurance amounts. As with the 90 day post discharge period, we believe that this comprehensive inclusion of Medicare Part A and Part B spending emphasizes the importance of care coordination in improving patient care. Encouraging delivery of coordinated care in an efficient manner over an extended time period is an important goal which can best be achieved through the inclusion of comprehensive Medicare Part A and Part B spending.

We also are proposing that transfers, readmissions, and additional admissions that began during the 90-day post discharge window of an index admission would be included in the episode used for calculating the measure.

We are proposing to exclude from the Medicare spending per beneficiary calculation episodes where at any time during the episode the beneficiary is not enrolled in both Medicare Part A and Medicare Part B, including if the beneficiary is enrolled in a Medicare Advantage plan at any time during the episode or becomes deceased. We also are proposing to exclude any episodes where the beneficiary is covered by the Railroad Retirement Board. We also propose to exclude any episodes where Medicare is a secondary payer. The rationale for exclusion of these episodes from the calculation of the Medicare spending per beneficiary is that we do not have full payment data to identify and standardize spending which would otherwise be attributable to these episodes.

• Adjusting the Medicare Payments Included in the Spending per Beneficiary Episode

Section 1886(o)(2)(B)(ii) of the Act requires that a Medicare spending per beneficiary measure adopted for the Hospital VBP Program be "adjusted for factors such as age, sex, race, severity of

illness, and other factors that the Secretary determines appropriate." Consistent with these statutory requirements, we are proposing to adjust the proposed Medicare spending per beneficiary measure for age and severity of illness. We are proposing to adjust for severity of illness based on the hierarchical condition categories (HCCs) for the period 90 days prior to the episode and based on the MS–DRG during the index admission. Adding the MS–DRG to the use of the HCC improves the severity of illness adjustment and better standardizes the data, allowing for more valid comparisons of Medicare spending per beneficiary amounts across hospitals. Note that we would exclude episodes where the beneficiary is not enrolled in both Medicare Part A and Medicare Part B, for the 90 days prior to the episode because we would not be able to capture all the data necessary for the severity of illness adjustment.

We are not proposing to adjust the Medicare spending per beneficiary for sex and race, consistent with our understanding of NQF's position strongly discouraging adjusting measures based on these factors.

In addition, we are proposing to exclude geographic payment rate differences (for example, based on the wage index and geographic practice cost index) in order to standardize the spending per beneficiary. Note, we are not proposing to adjust for geographic differences in spending that are unrelated to geographic payment rate differences. However, we seek comment on whether there are geographic factors other than payment rate differences that should be considered in the spending per beneficiary measure. We also propose to standardize spending by excluding the portion of IPPS payments resulting from the payment differentials caused by Hospital-Specific Rates, IME, and DSH. Note that we are not proposing to exclude spending for hospitals that are paid Hospital-Specific Rates, rather we are proposing to exclude the differential additional spending that results from the use of the Hospital-Specific Rates. Again, making these adjustments allows for more valid comparisons of Medicare spending per beneficiary amounts across hospitals. For example, without adjusting for geographic payment rate differences, a hospital might have higher or lower spending per beneficiary amounts compared to other hospitals based on its wage index and not its performance.

• Calculating a Hospital's Medicare Spending per Beneficiary Amount

For each subsection (d) hospital participating in the Hospital IQR Program, we are proposing to add together all the adjusted Medicare Part A and Part B payments, as defined above, included in all the Medicare spending per beneficiary episodes, as defined above, for that hospital. We would then divide this sum by the total number of Medicare Spending per Beneficiary episodes for that hospital. The resulting amount would constitute the hospital's Medicare spending per beneficiary amount for the period. The discharge period that we are proposing to apply the proposed measure for the FY 2014 Hospital IQR Program is May 15, 2012 through February 14, 2013.

• Calculating a Hospital's Medicare Spending per Beneficiary Ratio

We are proposing to calculate a hospital's Medicare spending per beneficiary ratio as the hospital's Medicare spending per beneficiary amount divided by the median Medicare spending per beneficiary amount across all hospitals.

As noted above, we are also proposing to adopt this proposed measure for the Hospital VBP Program FY 2014 measure set. The proposed method for scoring and incorporating this Medicare spending per beneficiary ratio into the hospital's total performance score for the Hospital VBP Program is fully described in section IV.B.3.b.(3)(C) of this proposed rule.

(C) Proposed New Web-Based Structural Measure

Structural measures assess the characteristics and capacity of the provider to deliver quality health care. In the FY 2009 IPPS final rule, we finalized the "Participation in a Systematic Database for Cardiac Surgery" measure (73 FR 48609) for the FY 2010 payment determination. This measure does not require the hospital to actually participate in a cardiac surgery registry, instead, it only requires the hospital to report whether or not it participates in a cardiac surgery registry. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43871 and 43872), we adopted two more structural measures: Participation in a Systematic Clinical Database Registry for Stroke Care; and Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care under the Hospital IQR Program for the FY 2011 payment determination. Based on public comments, we collect these structural measures once annually.

We are now proposing to include a new structural measure, Participation in a Systematic Clinical Database Registry for General Surgery, in the Hospital IQR Program beginning with the FY 2014 payment determination. The Participation in a Systematic Clinical Database Registry for General Surgery measure would require each hospital that participates in Hospital IQR Program to indicate whether it is participating in a Systematic Clinical Database Registry for General Surgery and, if so, to identify the registry. This measure, like two of the previously adopted structural measures on registry participation (Participation in a Systematic Clinical Database Registry for Stroke Care; and Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care), is an application of an NQF-endorsed measure (NQF #0493) "Participation by a physician or other clinician in a systematic clinical database registry that includes consensus endorsed quality measures" to the inpatient facility.

We recognize that the NQF has endorsed this measure for the physician/clinician setting, but believe that this measure is highly relevant to the hospital setting, in that participation in a systematic clinical database registry for various topics is quite common in hospitals. Therefore, we previously adopted the Stroke and Nursing Sensitive Care registry participation measures as applications of the measure appropriate to the hospital inpatient setting. We reviewed the NQF's consensus endorsed measures, as well as measures endorsed or adopted by another consensus organization, and were unable to identify any other measures specifically for participation in a systematic clinical database registry for general surgery that have been endorsed for the hospital inpatient setting. Having given due consideration to other measures that have been endorsed or adopted by a consensus entity, we are proposing to adopt an application of this non-NQF endorsed measure under the Secretary's authority to select non-NQF endorsed measures where such measures do not exist for a specified topic or medical topic. We are proposing to adopt the measure under the exception authority provided in section 1886 (b)(3)(B)(IX)(bb) of the Act. Additionally, we believe that, for the same reasons, the previously adopted structural measures for Stroke and Nursing Sensitive Care registries also meet the requirements under this authority and propose to continue collecting them on that basis.

We are proposing that annual data submission for this proposed structural

measure via a Web-based collection tool would begin in July 2012 with respect to the time period January 1, 2012, through June 30, 2012. We believe that participation in a registry provides hospitals with valuable ongoing quality improvement information and demonstrates a commitment to improve. Many registries also collect outcome data and provide feedback to hospitals about their performance. We invite public comment on this proposal to include this structural measure for the FY 2014 payment determination.

In summary, we are proposing to retire 8 measures from the measure set for the FY 2014 payment determination that was finalized in the FY 2011 IPPS/LTCH PPS final rule, and we are proposing to add 4 measures to the measure set for the FY 2014 payment determination: 2 HAI measures collected through the NHSN, 1 claims-based measure (Medicare Spending Per Beneficiary), and 1 structural measure, for a total of 56 measures for the FY 2014 Hospital IQR payment determination. These 56 measures are listed below.

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Topic	Proposed Hospital IQR Program Measures for FY 2014 Payment Determination Reflecting Proposed Retirement of 8 Measures and Proposed New Measures
Acute Myocardial Infarction (AMI)	
	• AMI-2 Aspirin prescribed at discharge
	• AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival
	• AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)
	• AMI-10 Statin Prescribed at Discharge
Heart Failure (HF)	
	• HF-1 Discharge instructions
	• HF-2 Evaluation of left ventricular systolic function
	• HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction
Pneumonia (PN)	
	• PN-3b Blood culture performed in the emergency department prior to first antibiotic received in hospital
	• PN-6 Appropriate initial antibiotic selection
Surgical Care Improvement Project (SCIP)	
	• SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision
	• SCIP INF-2: Prophylactic antibiotic selection for surgical patients
	• SCIP INF-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)
	• SCIP INF-4: Cardiac surgery patients with controlled 6AM postoperative serum glucose
	• SCIP INF-9: Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero
	• SCIP INF-10: Surgery patients with perioperative temperature management
	• SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period
	• SCIP INF -VTE-1: Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered
	• SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery
Mortality Measures (Medicare Patients)	
	• Acute Myocardial Infarction (AMI) 30-day mortality rate
	• Heart Failure (HF) 30-day mortality rate
	• Pneumonia (PN) 30-day mortality rate

Topic	Proposed Hospital IQR Program Measures for FY 2014 Payment Determination Reflecting Proposed Retirement of 8 Measures and Proposed New Measures
Patients' Experience of Care	
	● HCAHPS survey
Readmission Measure (Medicare Patients)	
	● Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure
	● Heart Failure 30-day Risk Standardized Readmission Measure
	● Pneumonia 30-day Risk Standardized Readmission Measure
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures	
	● PSI 06: Iatrogenic pneumothorax, adult
	● PSI 11: Post Operative Respiratory Failure
	● PSI 12: Post Operative PE or DVT
	● PSI 14: Postoperative wound dehiscence
	● PSI 15: Accidental puncture or laceration
	● IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume)
	● IQI 19: Hip fracture mortality rate
	● Complication/patient safety for selected indicators (composite)
	● Mortality for selected medical conditions (composite)
AHRQ PSI and Nursing Sensitive Care	
	● PSI 04 Death among surgical inpatients with serious treatable complications
Structural measures	
	● Participation in a Systematic Database for Cardiac Surgery
	● Participation in a Systematic Clinical Database Registry for Stroke Care
	● Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care
	● Participation in a Systematic Clinical Database Registry for General Surgery**
Healthcare-Associated Infections	
	● Central Line Associated Bloodstream Infection
	● Surgical Site Infection*
	● Central Line Insertion Practices Percentage**
	● Catheter-Associated Urinary Tract Infection**
Hospital Acquired Condition Measures	
	● Foreign Object Retained After Surgery
	● Air Embolism
	● Blood Incompatibility
	● Pressure Ulcer Stages III & IV
	● Falls and Trauma: (Includes: Fracture Dislocation Intracranial

Topic	Proposed Hospital IQR Program Measures for FY 2014 Payment Determination Reflecting Proposed Retirement of 8 Measures and Proposed New Measures
	Injury Crushing Injury Burn Electric Shock)
	• Vascular Catheter-Associated Infection
	• Catheter-Associated Urinary Tract Infection (UTI)
	• Manifestations of Poor Glycemic Control
Emergency Department Throughput	
	• ED-1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital*
	• ED-2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status*
Prevention: Global Immunization Measures	
	• Immunization for Influenza *
	• Immunization for Pneumonia*
Cost Efficiency	
	• Medicare Spending per Beneficiary**

* Measures finalized in the FY 2011 IPPS/LTCH PPS final rule for the FY 2014 payment determination
** Additional measures proposed in this proposed rule for FY 2014 payment determination

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c. Proposed Hospital IQR Program Quality Measures for the FY 2015 Payment Determination

(1) Proposed Retention of FY 2014 Payment Determination Measures for the FY 2015 Payment Determination

We generally retain the Hospital IQR Program measures from one year to the next. Consistent with this approach, we are proposing to retain all of the proposed measures for the FY 2014 payment determination, if finalized, for the FY 2015 payment determination. We invite public comment on this proposal.

(2) Proposed New Hospital IQR Program Measures for the FY 2015 Payment Determination

(A) Proposed New CDC/NHSN-Based Healthcare-Associated Infection (HAI) Measures for the 2015 Payment Determination

For the FY 2015 payment determination, we are proposing to adopt three additional HAI measures that are currently collected by CDC via the NHSN. These measures are: (1) Methicillin-resistant Staphylococcus Aureus (MRSA) Bacteremia measure; (2) C. *Difficile* SIR; and (3) Healthcare Personnel (HCP) Influenza Vaccination and the specifications for these 3 measures are available at *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.* Like the CLIP and the CAUTI measures that we are proposing for the FY 2014 payment determination, all three proposed HAI measures are high priority HAI measures listed in the HHS Action Plan to Prevent HAIs and were listed in previous rulemaking as possible quality measures for future payment determinations.

Our review indicated that there are no measures for MRSA or C. *Difficile* SIR that have been endorsed by the NQF or another consensus entity for the hospital inpatient setting. Therefore, we are proposing to adopt this non-NQF-endorsed measure under the Secretary's authority to select non-NQF endorsed measures where such measures do not exist for a specified topic or medical topic. We are proposing to adopt these two CDC-developed measures (MRSA and C. *Difficile* SIR) under the exception authority provided in section 1886 (b)(3)(B)(IX)(bb) of the Act.

The HCP Influenza Vaccination measure is NQF-endorsed (NQF #0431) for the hospital setting. Therefore, this measure meets the requirement for measure selection under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act.

(1) Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia Measure

There are different types of staphylococcus aureus bacteria, commonly called "staph." Staph bacteria are normally found on the skin or in the nose. The bacteria are generally harmless unless they enter the body through a cut or other wound, and even then they usually cause only minor skin problems in healthy people. MRSA infection is caused by a strain of staph bacteria that has become resistant to the antibiotics commonly used to treat ordinary staph infections. Older adults with weakened immune systems and patients in hospital or nursing home settings are most vulnerable to MRSA infections. Health care-associated MRSA infections typically are associated with invasive procedures or devices, such as surgeries, intravenous tubing, urinary catheters, or artificial joints. MRSA infections account for about 60 percent of skin infections seen in United States emergency departments and invasive MRSA infections may cause about 18,000 deaths during a hospital stay a year.[13] Currently, there are 6 States that require facilities to report MRSA

[13] Catherine Liu, Arnold Bayer, *et al.,* Clinical practice Guidelines by the for the treatment of Methicillin-Resistant Staphylococcus Aureus Infections in Adult and Children. Infectious Disease Society of America 2011; 52:e18.

information to NHSN. As stated above, we were unable to identify any other measures specifically for MRSA that have been endorsed by the NQF for the hospital inpatient setting. We found no other measures that have been endorsed or adopted by a consensus entity. Therefore, we are proposing to adopt this non-NQF-endorsed and CDC-developed measure under the Secretary's authority to select non-NQF endorsed measures where such measures do not exist for a specified topic or medical topic, under the exception authority provided in section 1886 (b)(3)(B)(IX)(bb) of the Act. The proposed reporting mechanism for the MRSA measure is discussed in greater detail in section IV.A.5.i. of this proposed rule. We invite public comment on this proposed HAI measure.

(2) C. *Difficile* SIR Measure

Clostridium *Difficile* (C. *difficile*) is a bacterium that can cause symptoms ranging from diarrhea, pseudo-membranous colitis, and toxic megacolon to life-threatening sepsis and even death. Illness from C. *Difficile* most commonly affects older adults in hospitals or in long term care facilities where germs spread easily, antibiotic use is common and people are especially vulnerable to infection. Illness from C. *Difficile* typically occurs after use of antibiotic medications. C. *Difficile* spreads mainly on hands from person to person, but also on commonly touched services such as cart handles, bedrails, bedside tables, toilets, sinks, stethoscopes, thermometers, and telephones. In recent years, C. *Difficile* infections have become more frequent, more severe and more difficult to treat. Each year, tens of thousands of people in the United States get sick from C. *Difficile,* including some otherwise healthy people who are not hospitalized or taking antibiotics. Healthcare providers have become more aware of the C. *Difficile* infection and therefore, more testing is being done for symptomatic patients. The C. *Difficile* pathogens may require specialized monitoring to evaluate if intensified infection control efforts are required to reduce the occurrence of these organisms and related infections. Currently, there are 3 States that require facilities to report C. *Difficile* data to NHSN. Our goal for this proposed C. *Difficile* SIR measure is to provide a common mechanism (CDC/NHSN) for all hospitals including hospitals participating in the Hospital IQR Program to report and analyze these data that will inform infection control staff of the impact of targeted prevention efforts. The NHSN is listed in the HHS Action Plan to Prevent HAIs as the data source for HAI measures. As stated above, we were unable to identify any other measures specifically for C. *Difficile* SIR that have been endorsed by the NQF for the hospital inpatient setting. We found no other measures that have been endorsed or adopted by a consensus entity. Therefore, we are proposing to adopt this non-NQF-endorsed and CDC-developed measure under the Secretary's authority to select non-NQF endorsed measures where such measures do not exist for a specified topic or medical topic, under the exception authority provided in section 1886 (b)(3)(B)(IX)(bb) of the Act. We have chosen to leverage existing NHSN reporting system to collect HAI measures since we have already established a mechanism for reporting to the NHSN.

The proposed reporting mechanism for these proposed HAI measures is discussed in greater detail in section IV.A.5.i. of this proposed rule. We invite public comment on these proposed HAI measures.

(3) Healthcare Personnel (HCP) Influenza Vaccination (NQF # 0431)

For the FY 2015 payment determination, we are proposing to adopt one additional HAI measure that is currently collected by CDC via the NHSN: Healthcare Personnel (HCP) Influenza Vaccination (NQF # 0431). This measure assesses the percentage of HCP employed at the facility that received a prophylactic vaccination for influenza. This measure is NQF endorsed, and therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act.

Rates of serious illness and death resulting from influenza and its complications are increased in high-risk populations such as persons over 50 years or under four years of age, and persons of any age who have underlying conditions that put them at an increased risk. HCP can acquire influenza from patients and can transmit influenza to patients and other HCP. Many HCP provide care for, or are in frequent contact with, patients with influenza or patients at high risk for complications of influenza. The involvement of HCP in influenza transmission has been a long-standing concern.[14] [15] [16]

Vaccination is an effective preventive measure against influenza, and can prevent many illnesses, deaths, and losses in productivity.[17] HCP are considered a high priority for expanding influenza vaccine use. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients and reduce disease burden and healthcare costs. Results of several studies indicate that higher vaccination coverage among HCP is associated with lower incidence of nosocomial influenza.[18] [19] [20] Such findings have led some to call for mandatory influenza vaccination of HCP.[21] [22] [23] [24] [25]

Until recently, vaccination coverage among HCP has been well below the national Healthy People 2010 target of 60 percent,[26] but preliminary data suggest 62 percent of HCP reported receiving seasonal influenza vaccine in

[14] Maltezou HC, Drancourt M., Nosocomial influenza in children. Journal of Hospital Infection 2003; 55:83–91.

[15] Hurley JC, Flockhart S., An influenza outbreak in a regional residential facility. Journal of Infection Prevention 2010; 11:58–61.

[16] Salgado CD, Farr BM, Hall KK, Hayden FG., Influenza in the acute hospital setting. The Lancet Infectious Diseases 2002; 2:145–155.

[17] Wilde JA, McMillan JA, Serwint J, Butta J, O'Riordan MA, Steinhoff MC., Effectiveness of influenza vaccine in health care professionals: a randomized trial. The Journal of the American Medical Association 1999; 281:908–913.

[18] Salgado CD, Giannetta ET, Hayden FG, Farr BM., Preventing influenza by improving the vaccine acceptance rate of clinicians. Infection Control and Hospital Epidemiology 2004; 25: 923–928.

[19] Potter J, Stott DJ, Roberts MA, *et al.,* Influenza vaccination of health-care workers in long-term-care hospitals reduces the mortality of elderly patients. Journal of Infectious Diseases 1997; 175:1–6.

[20] Hayward AC, Harling R, Wetten S, *et al.,* Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. British Medical Journal 2006; 333:1241–1246.

[21] Talbot TR, Bradley SF, Cosgrove SE, *et al.,* SHEA position paper: Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. Infection Control and Hospital Epidemiology 2005; 26:882–890.

[22] American College of Physicians (ACP), ACP policy on influenza vaccination of health care workers. *http://www.acponline.org/running_practice/quality_improvement/projects/adult_immunization/flu_hcw.pdf.*

[23] Greene LR, Cain TA, Dolan SA *et al.,* APIC position paper: influenza immunization of healthcare personnel. Association of Professionals in Infection Control (APIC). November 2008. *http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Influenza/APIC_Position_Paper_Influenza_11_7_08final_revised.pdf*

[24] National Patient Safety Foundation (NPSF), Mandatory flu vaccinations for healthcare workers. Press Release, November 18, 2009. *http://www.npsf.org/pr/pressrel/2009-11-18.php.*

[25] Infectious Diseases Society of America (IDSA), IDSA policy on mandatory immunization of health care workers against seasonal and 2009 H1N1 influenza. Infectious Diseases Society of America (IDSA). September 30, 2009. *http://www.idsociety.org/HCWimmunization/.*

[26] Walker FJ, Singleton JA, Lu P, Wooten KG, Strikas RA., Influenza vaccination of healthcare workers in the United States, 1989–2002. Infection Control and Hospital Epidemiology 2006; 27:257–265.

2009–2010.[27] Only 37 percent reported receiving the 2009 pandemic A/H1N1 vaccine.[28]

HCP refers to all personnel working in healthcare settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air.[29] HCP may include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (for example, clerical, dietary, housekeeping, laundry, security, maintenance, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients. Settings in which HCP may work include, but are not limited to, acute care hospitals, long-term care facilities, skilled nursing facilities, rehabilitation centers, physicians' offices, urgent care centers, outpatient clinics, home health agencies, and emergency medical services.

Currently, four States have "offer" laws for influenza vaccination of HCP, meaning that vaccine must be offered to HCP by healthcare facilities; and three States (Alabama, California, and New Hampshire) have "ensure" laws for influenza vaccination of HCP, meaning that vaccination of non-immune HCP is mandatory in the absence of a specified exemption or refusal; and, additionally, numerous hospitals and other healthcare facilities have established policies requiring mandatory influenza vaccination of their HCP.[30]

Currently, no State requires that hospitals report this measure to NHSN. However, approximately 13 hospitals (including long term acute care and rehabilitation), outpatient hemodialysis centers, long term care facilities, and ambulatory surgical centers are currently reporting HCP immunization data to NHSN. In September 2009, CDC released the Healthcare Personnel Safety (HPS) Component of NHSN, which complements Patient Safety and Biovigilance components available in NHSN. The HPS Component replaced CDC's National Surveillance System for Health Care Workers (NaSH) and is comprised of two modules: the Blood/Body Fluid Exposure Module and the Influenza Vaccination and Management and Exposure Module.[31] Currently, participation in either module is voluntary. The current Influenza Vaccination and Management and Exposure Module may soon offer options for healthcare facilities to submit vaccination summary data. NHSN plans to partner with vendor-based surveillance systems to permit periodic data extractions into NHSN.

The modules feature basic, custom, and advanced analysis capabilities available in real-time, which allow individual healthcare facilities to compile and analyze their own data, as well as benchmark these results to aggregate NHSN estimates. The HPS Component can assist participating facilities in developing surveillance and analysis capabilities to permit the timely recognition of HCP safety problems and prompt interventions with appropriate measures. Influenza vaccination data submitted to CDC will ultimately capture regional trends on the yearly uptake of the vaccine, prophylaxis and treatment for healthcare personnel, as well as the elements within yearly influenza campaigns that succeed or require improvement. At the State and national levels, the HPS Component will aid in monitoring rates and trends.

We are proposing to adopt the Healthcare Provider Influenza Vaccination measure that is currently collected by the CDC via the NHSN because of its importance in preventing influenza not only among healthcare workers but also patients that they attend.. As stated earlier, this measure assesses the percent of Healthcare Personnel employed at the facility that received a prophylactic vaccination for influenza. Detailed specifications for the proposed measure are available at: *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.* As we also stated above, this measure is NQF-endorsed for the hospital setting. The proposed reporting mechanism for this proposed HAI measure is discussed in greater detail in section IV.A.5.i. of this proposed rule. We invite public comment on this proposed HAI measure.

(B) Proposed New Chart-Abstracted Measures for the FY 2015 Payment Determination

We are proposing to adopt two sets of chart-abstracted measures for the FY 2015 payment determination: the Stroke and Venous Thromboembolism (VTE) measure sets. All of these proposed measures have either previously been proposed for the Hospital IQR Program, or have been listed as being under consideration for future adoption into the program. In addition, with one exception (STK–1: VTE Prophylaxis), all of the measures in these two measure sets have been electronically specified and are among the measures adopted for the EHR Incentive Program for eligible hospitals. While we are proposing to adopt these for chart-abstracted submission in 2013 for the FY 2015 payment determination, we believe that by a future date, such as 2015, hospitals will be able to switch to EHR-based submission of these and all other chart-abstracted measures submitted for the Hospital IQR Program, and, as we discuss in greater detail below, we intend to work toward this goal over the next few years.

The Stroke measure set we are proposing to adopt consists of 8 measures; and the VTE measure set consists of 6 measures. Both measure sets are NQF-endorsed and their specifications are currently available in the Specifications Manual, which can be found on QualityNet. We believe that both of the proposed measure sets compliment the data elements in our current SCIP VTE and AMI measure sets.

(i) Stroke Measure Set

Stroke is a topic of great relevance to the Medicare population due to its impact on morbidity and mortality, and it is an area with great potential for quality improvement for hospitals caring for stroke patients. Stroke is the third most common cause of death in the United States and is one of the top 20 conditions contributing to Medicare costs. Approximately 8 to 12 percent of ischemic strokes are fatal,[32] and

[27] *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e209a1.htm.* Influenza Vaccination of Health-Care Personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices.

[28] Centers for Disease Control and Prevention., Interim results: Influenza A (H1N1) 2009 and Monovalent Seasonal Influenza Vaccination Coverage Among Health-Care Personnel—United States August 2009–January 2010. Morbidity and Mortality Weekly Report (MMWR); 59:357–362. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5912a1.htm.*

[29] Adapted from: Pearson ML., Bridges CB., Harper SA.,: Influenza vaccination of health-care personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). Morbidity and Mortality Weekly Report (MMWR) 2006; 55:1–16. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm.*

[30] For additional information regarding healthcare facilities' influenza vaccine policies, please see: *http://www.immunize.org/honor%2Droll/.*

[31] Available at: *http://www.cdc.gov/nhsn/hps.htm.*

[32] American Heart Association, Heart Disease and Stroke Statistics—2009 Update. American Heart Association, 2009: p. 1–36.

mortality following stroke is influenced by the quality of care provided to patients during their initial hospitalization.[33] In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43873), we listed 8 Stroke measures as being under consideration for adoption for the FY 2012 Hospital IQR payment determination. Numerous commenters encouraged us to adopt the listed stroke measures which they see as evidence-based measures that accurately measure the care of the stroke patient (74 FR 43875 through 43876). Commenters believed that the measures are widely recognized for their roles in minimizing secondary strokes and other complications.

We are proposing to adopt a stroke measure set with 8 NQF-endorsed process-of-care measures for the FY 2015 payment determination. The table below lists and describes each of these eight proposed measures.

8 Proposed Stroke Measures	
STK-1: Venous Thromboembolism (VTE) Prophylaxis for patients with ischemic or hemorrhagic stroke (NQF #0434)	Percent of patients with an ischemic stroke or a hemorrhagic stroke and who are non-ambulatory should start receiving DVT prophylaxis by end of hospital day two.
STK-2: Ischemic stroke patients discharged on antithrombotic therapy. (NQF #0435)	Percent of patients with an ischemic stroke prescribed antithrombotic therapy at discharge.
STK-3: Anticoagulation therapy for atrial fibrillation/flutter. (NQF #0436)	Percent of patients with an ischemic stroke with atrial fibrillation discharged on anticoagulation therapy.
STK-4: Thrombolytic Therapy for Acute ischemic stroke patients. (NQF #0437)	Percent of acute ischemic stroke patients who arrive at the hospital within 120 minutes (2 hours) of time last known well and for whom IV t-PA was initiated at this hospital within 180 minutes (3 hours) of time last known well.
STK-5: Antithrombotic therapy by the end of hospital day two. (NQF #0438)	Percent of patients with ischemic stroke who receive antithrombotic therapy by the end of hospital day two.
STK-6: Discharged on statin medication. (NQF #0439)	Percent of ischemic stroke patients with LDL >/= 100 mg/dL, or LDL not measured, or, who were on cholesterol reducing therapy prior to hospitalization are discharged on a statin medication.
STK-8: Stroke education. (NQF #0440)	Percent of patients with ischemic or hemorrhagic stroke or their caregivers who were given education or educational materials during the hospital stay addressing all of the following: personal risk factors for stroke, warning signs for stroke, activation of emergency.
STK-10: Assessed for rehabilitation services. (NQF #0441)	Percent of patients with an ischemic stroke or hemorrhagic stroke who were assessed for rehabilitation services.

Because the NQF is the entity that holds a contract with the Secretary under section 1890(a) of the Act, measures that are endorsed by the NQF meet the requirement for measure selection under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. Aside from the consideration of NQF-endorsement, we believe that the inclusion of the proposed stroke measure set in the Hospital IQR Program would provide a comprehensive view of how well stroke care is being managed in a hospital setting. As stated earlier, detailed measure specifications for these

[33] Weir, N.U., *et al.,* Variations between countries in outcome after stroke in the International Stroke Trial (IST). Stroke, 2001. 32(6): p. 1370–7.

8 proposed measures are available in the Specifications Manual located in QualityNet. We invite public comment on the proposed stroke measure set.

(ii) VTE Measure Set

It is widely agreed that VTE is the number one preventable cause of hospital death in the United States and the cost of VTE when it occurs is very high. A recent study from AHRQ in Health Affairs highlighted that when an acute VTE event occurs, it increases the costs of care by 25 percent. In 2008, the Surgeon General issued a Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism. (This document can be found at: *http://www.surgeongeneral.gov/topics/deepvein/calltoaction/call-to-action-on-dvt-2008.pdf.)* VTE prevention with pharmacologic agents can impact the cost effectiveness of care. Specifically, patients who received anti-coagulant medication during hospitalization have less likelihood of recurrence of VTEs upon discharge to home. Parenteral anticoagulation is the first line of therapy because of its rapid onset of action. Because the oral anticoagulant medication has a very slow onset of action, it cannot be used as mono-therapy for acute VTE. A minimum of five days of parenteral anticoagulation is recommended as "overlap therapy" while oral anticoagulant medication is being initiated. More thrombotic complications and higher costs are associated with treatment in patients demonstrating a subtherapeutic aPTT. Unfractionated Heparin (UFH) Dosages/Platelet Count Monitoring by Protocol (or Nomogram) has significantly advanced the use of UFH with the demonstrated ability to achieve therapeutic aPTTs more rapidly than with standard UFH dosing. When this occurs, patients can be discharged sooner. However, anticoagulation therapy poses risks to patients and often leads to adverse drug events due to complex dosing, requisite follow-up monitoring and inconsistent patient compliance. The use of standardized practices for anticoagulation therapy that includes patient/caregiver involvement may reduce the risk of adverse drug events.

The Hospital IQR Program currently has 2 measures of VTE prophylaxis for surgical patients (SCIP–VTE–1: Venous thromboembolism (VTE) prophylaxis ordered for surgery patients; and SCIP–VTE–2: VTE prophylaxis within 24 hours pre/post surgery) in the SCIP measure set. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43873), we listed 5 VTE measures (VTE–1; Venous thromboembolism prophylaxis; VTE–3: Venous thromboembolism patients with anticoagulation overlap therapy; VTE–4: Venous thromboembolism patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol; VTE–5: Venous thromboembolism discharge instructions; and VTE–6: Incidence of potentially-preventable venous Thromboembolism) as possible new quality measures for the FY 2012 payment determination. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50213 through 50218), we listed 6 VTE measures (VTE–1; Venous thromboembolism prophylaxis; VTE–2: Intensive care unit venous thromboembolism prophylaxis; VTE–3: Venous thromboembolism patients with anticoagulation overlap therapy; VTE–4: Venous thromboembolism patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol; VTE–5: Venous thromboembolism discharge instructions; and VTE–6: Incidence of potentially-preventable venous thromboembolism) as measures we were considering for possible future adoption into the program.

We are now proposing to adopt for the FY 2015 Hospital IQR measure set 6 VTE measures which are aimed at preventing the incidence of potentially preventable VTE. These 6 measures are listed and described below.

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6 Proposed Venous Thromboembolism (VTE) Measures	
VTE-1: Venous thromboembolism prophylaxis (NQF #0371)	Percent of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.
VTE-2: Intensive care unit venous thromboembolism prophylaxis (NQF #0372)	Percent of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).
VTE-3: Venous thromboembolism patients with anticoagulation overlap therapy (NQF #0371)	Percent of patients diagnosed with confirmed VTE who received an overlap of parenteral (intravenous [IV] or subcutaneous [subcu]) anticoagulation and warfarin therapy. For patients who received less than five days of overlap therapy, they must be discharged on both medications. Overlap therapy must be administered for at least five days with an international normalized ratio (INR) = 2 prior to discontinuation of the parenteral anticoagulation therapy or the patient must be discharged on both medications.
VTE-4: Venous thromboembolism patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol (NQF #0371)	Percent of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol.
VTE-5: Venous thromboembolism discharge instructions (NQF #0371)	Percent of patients diagnosed with confirmed VTE that are discharged to home, to home with home health or home hospice on warfarin with written discharge instructions that address all four criteria: compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/interactions.
VTE-6: Incidence of potentially-preventable venous Thromboembolism (NQF #0371)	Percent of patients diagnosed with confirmed VTE during hospitalization (not present on arrival) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date.

These 6 measures were endorsed in a 2008 NQF project titled: National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism: Additional Performance Measures. Because the NQF is the entity that holds a contract with the Secretary under section 1890(a) of the Act, measures that are endorsed by the NQF meet the requirement for measure selection under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. Aside from the consideration of NQF-endorsement, we believe that the inclusion of the VTE measure set in the Hospital IQR Program would provide a comprehensive view of how well VTE care is being managed in a hospital setting. Detailed measure specifications for these 6 proposed measures are available in the Specifications Manual located on QualityNet. We invite public comment on the proposed VTE measure set.

In summary, for the FY 2015 payment determination, we are proposing to retain all of the FY 2014 measures (56 measures if all of the measures are finalized), to adopt 3 HAI measures, and 14 chart-abstracted measures for a total of 73 measures for the FY 2015 payment determination. The measures proposed for the Hospital IQR Program for the FY 2015 payment determinations are set forth below.

Topic	Proposed Hospital IQR Program Measures for FY 2015 Payment Determination
Acute Myocardial Infarction (AMI) Measures	
	● AMI-2 Aspirin prescribed at discharge
	● AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival
	● AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)
	● AMI-10 Statin Prescribed at Discharge
Heart Failure (HF) Measures	
	● HF-1 Discharge instructions
	● HF-2 Evaluation of left ventricular systolic function
	● HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction
Stroke Measure Set	
	● STK-1 VTE prophylaxis**
	● STK-2 Antithrombotic therapy for ischemic stroke**
	● STK-3 Anticoagulation therapy for Afib/flutter**
	● STK-4 Thrombolytic therapy for acute ischemic stroke**
	● STK-5 Antithrombotic therapy by the end of hospital day 2**
	● STK-6 Discharged on Statin**
	● STK-8 Stroke education**
	● STK-10 Assessed for rehab**
VTE Measure Set	
	● VTE-1 VTE prophylaxis**
	● VTE-2 ICU VTE prophylaxis**
	● VTE-3 VTE patients with anticoagulation overlap therapy**
	● VTE-4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol**
	● VTE-5 VTE discharge instructions**
	● VTE-6 Incidence of potentially preventable VTE**
Pneumonia (PN) Measures	
	● PN-3b Blood culture performed in the emergency department prior to first antibiotic received in hospital
	● PN-6 Appropriate initial antibiotic selection
Surgical Care Improvement Project (SCIP) Measures	
	● SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision
	● SCIP INF-2: Prophylactic antibiotic selection for surgical patients
	● SCIP INF-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)
	● SCIP INF-4: Cardiac surgery patients with controlled 6AM

Topic	Proposed Hospital IQR Program Measures for FY 2015 Payment Determination
	postoperative serum glucose
	● SCIP INF-9: Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero
	● SCIP INF-10: Surgery patients with perioperative temperature management
	● SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period
	● SCIP INF -VTE-1: Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered
	● SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery
Mortality Measures (Medicare Patients)	
	● Acute Myocardial Infarction (AMI) 30-day mortality rate
	● Heart Failure (HF) 30-day mortality rate
	● Pneumonia (PN) 30-day mortality rate
Patients' Experience of Care Measure	
	● HCAHPS survey
Readmission Measures (Medicare Patients)	
	● Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure
	● Heart Failure 30-day Risk Standardized Readmission Measure
	● Pneumonia 30-day Risk Standardized Readmission Measure
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures	
	● PSI 06: Iatrogenic pneumothorax, adult
	● PSI 11: Post Operative Respiratory Failure
	● PSI 12: Post Operative PE or DVT
	● PSI 14: Postoperative wound dehiscence
	● PSI 15: Accidental puncture or laceration
	● IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume)
	● IQI 19: Hip fracture mortality rate
	● Complication/patient safety for selected indicators (composite)
	● Mortality for selected medical conditions (composite)
AHRQ PSI and Nursing Sensitive Care	
	● PSI-4 Death among surgical inpatients with serious treatable complications
Structural Measures	
	● Participation in a Systematic Database for Cardiac Surgery
	● Participation in a Systematic Clinical Database Registry for Stroke Care

Topic	Proposed Hospital IQR Program Measures for FY 2015 Payment Determination
	● Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care
	● Participation in a Systematic Clinical Database Registry for General Surgery*
Healthcare-Associated Infections Measures	
	● Central Line Associated Bloodstream Infection
	● Surgical Site Infection
	● Central Line Insertion Practice Percentage*
	● Catheter-Associated Urinary Tract Infection*
	● MRSA Bacteremia**
	● Clostridium Difficile (C.Diff)**
	● Healthcare Personnel Influenza Vaccination**
Hospital Acquired Condition Measures	
	● Foreign Object Retained After Surgery
	● Air Embolism
	● Blood Incompatibility
	● Pressure Ulcer Stages III & IV
	● Falls and Trauma: (Includes: Fracture Dislocation Intracranial Injury Crushing Injury Burn Electric Shock)
	• Vascular Catheter-Associated Infection
	● Catheter-Associated Urinary Tract Infection (UTI)
	● Manifestations of Poor Glycemic Control
Emergency Department Throughput Measures	
	● ED-1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital
	● ED-2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status
Prevention: Global Immunization Measures	
	● Immunization for Influenza
	● Immunization for Pneumonia
Cost Efficiency	
	● Medicare Spending per Beneficiary*

* New proposed quality measures for the FY 2014 payment determination
** New Proposed quality measures for FY 2015 payment determination

4. Possible New Quality Measures and Measure Topics for Future Years

Looking forward, we anticipate that as EHR technology evolves, and more infrastructure is put in place, we will have the capacity to accept electronic reporting of all of the clinical chart-abstracted quality measures that are currently in the Hospital IQR Program or have been proposed for adoption into the program. We intend for this future progress to significantly reduce the administrative burden on hospitals under the Hospital IQR Program. We recognize that considerable work needs to be done by measure owners and developers to make this possible with respect to the clinical quality measures that we proposed. This includes completing electronic specifications for measures, pilot testing, reliability and validity testing, and implementing such specifications into EHR technology to capture and calculate the results, and implementing the systems. We believe that at a future date, such as 2015, CMS and hospitals will be able to switch to complete EHR-based reporting of all chart-abstracted measures to CMS for the Hospital IQR Program, and we intend to work diligently toward this goal. We believe this will simplify measure collection and submission for the Hospital IQR Program, and will reduce the burden on hospitals. We invite public comment and suggestions on this topic.

In future rules, it is our intention to propose to adopt outcome measures for stroke and joint replacement surgery which we have developed and anticipate submitting for NQF review. In addition, we intend to propose additional HAI measures as they gain NQF endorsement. We also invite public comment on the following quality measures and topics set out below that we are considering for the future. We seek to limit the number of chart-abstracted measures and topics in the near future, in order to facilitate the transition to EHR-based reporting.

Possible Hospital IQR Program Future Measures and Topics	
Measurement Topic	**Measure Title/ Description/Concept**
Mortality/Complications	
	● Acute stroke 30-day mortality rate
	● Total Hip and Total Knee arthroplasty 30-day complications
Readmissions	
	● Stroke 30-Day Risk Standardized Readmission Measure
	● Total Hip and Total Knee Arthroplasty 30-Day Risk Standardized Readmission Measure
Patient Safety	
	● Surgical checklist use for surgical procedures
	● NQF approved Serious Reportable Events
Medication Safety	
	● Universal Documentation and Verification of Current Medications in the Medical Record
	● Drug-Drug interaction
	● Medication Reconciliation
Surgical Outcome Measures	
	● Lower Extremity Bypass Complications
	● ICD Complications
	● Risk Adjusted Case Mix Adjusted Elderly surgery outcomes
	● Risk Adjusted Case Mix Adjusted Colorectal surgery outcomes
Healthcare-Associated Infections	
	● Ventilator Associated Pneumonia
	● Post Procedure Pneumonias
	● Multi Drug Resistant Organisms—VRE, Klebsiella, Acinetobacter
Readmissions	
	● COPD 30-day Risk Standardized Readmission Rate
	● CABG 30-day Risk Standardized Readmission Rate
	● Other Vascular Condition 30-day Risk Standardized Readmission
	● Percutaneous Coronary Intervention (PCI) 30-day Risk Standardized Readmission Rate
	● All-Patient Condition-Specific Readmission Rates for AMI, Heart Failure, Pneumonia, CABG, COPD, PCI, other vascular conditions
	● All-condition 30-day readmission rate
Average Length of Stay	
	● Overall inpatient hospital average length of stay (ALOS) and ALOS by medical service category
Mortality	

Possible Hospital IQR Program Future Measures and Topics	
Measurement Topic	**Measure Title/ Description/Concept**
	● 30-day Risk Standardized Mortality Rate following PCI for STEMI/shock patients.
	● 30-day risk-standardized mortality rate following PCI for non-STEMI/non-shock patients.
SCIP	
	● Short Half-Life prophylactic administered preoperatively redosed within 4 hours after preoperative dose
Care Coordination	
	● Cardiac Rehabilitation Referral for AMI, HF, Cardiac Surgery
Heart Failure	
	● Symptom and Activity Assessment
	● Symptom Management
	● Patient Education
	● Combination Medical Therapy for LVSD
	● Beta Blocker Therapy for LVSD
	● Counseling Regarding ICD for Patients with LVSD
Tobacco & Alcohol Cessation	
	● TAM-1: Tobacco Use Screening
	● TAM-2: Tobacco Use Treatment
	● TAM-3: Tobacco Use Treatment Management at Discharge
	● TAM-4: Assessing Status after Discharge
	● TAM-5: Alcohol Use Screening
	● TAM-6: Alcohol Use Brief Intervention
	● TAM-7: Alcohol and other Drug dependence-Treatment Management at Discharge
	● TAM-8: Substance Use - Assessing Status after Discharge
Nursing Sensitive (remainder of measures)	
	● NSC-2: Patients surveyed on an eligible reporting unit that have at least one stage II or greater [National Ulcer Advisory Panel (NPUAP)] nosocomial pressure ulcer on the day of the prevalence study
	● NSC-3: Number of patient falls, with or without injury to the patient, by type of Unit during the calendar month x 1000.
	● NSC-4: Number of patient falls with an injury level of minor or greater by Type of Unit during the calendar month x 1,000.
	● NSC-5: Patients surveyed on the eligible reporting unit that have a vest restraint and/or limb restraint (upper or lower or both) on the day of the prevalence study
	● NSC-12: Number of productive hours worked as specified in the Set Measure Identifier

Possible Hospital IQR Program Future Measures and Topics	
Measurement Topic	**Measure Title/ Description/Concept**
	• NSC-13: Total number of productive hours worked by nursing staff (stratified by type of certification RN, LPN/LVN, UAP) with direct patient care responsibilities by Type of Unit during the calendar month.
	• NSC-14: Nursing satisfaction survey
	• NSC 15: The total number of voluntary separations (as specified under the Performance Measure Identifier and Description above) during the calendar month
Cardiac Surgery measures	
	• Post-operative Renal Failure
	• Surgical Re-exploration
	• Anti-Platelet Medication at Discharge
	• Beta Blockade at Discharge
	• Anti-Lipid Treatment Discharge (Statin at Discharge)
	• Risk-Adjusted Operative Mortality for CABG
	• Risk-Adjusted Operative Mortality for Aortic Valve Replacement (AVR)
	• Risk-Adjusted Operative Mortality for Mitral Valve Replacement/Repair (MVR)
	• Risk-Adjusted Operative Mortality MVR+CABG Surgery
	• Risk-Adjusted Operative Mortality for AVR+CABG
	• Surgical Volume - a. Isolated Coronary Artery Bypass Graft (CABG) Surgery, b. Valve Surgery, c. CABG+Valve Surgery
	• Timing of Antibiotic Prophylaxis for Cardiac Surgery Patients
	• Selection of Antibiotic Prophylaxis for Cardiac Surgery Patients
	• Pre-Operative Beta Blockade
	• Duration of Prophylaxis for Cardiac Surgery Patients
	• Prolonged Intubation (ventilation)
	• Deep Sternal Wound Infection Rate
	• Stroke/Cerebrovascular Accident
	• CABG Composite Score

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5. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (II) of the Act state that the applicable percentage increase, for FY 2007 and each subsequent fiscal year, shall be reduced by 2.0 percentage points (or, beginning with FY 2015, by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit quality data in a form and manner, and at a time, specified by the Secretary. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. CMS requires that hospitals submit data in accordance with the specifications for the appropriate discharge periods. Hospitals submit quality data through the secure portion of the QualityNet Web site (formerly known as QualityNet Exchange) (*https://www.QualityNet.org*). This Web site meets or exceeds all current Health Insurance Portability and Accountability Act requirements for security of protected health information.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural requirements. Hospitals choosing to participate in the Hospital IQR Program must also meet specific data collection, submission, and validation requirements.

b. Procedural Requirements for FY 2012 Payment Determinations and Subsequent Years

The proposed Hospital IQR Program procedural requirements are, for the most part, the same as the procedures adopted in the FY 2011 IPPS/LTCH PPS final rule for the Hospital IQR Program. Hospitals must comply with the following procedural requirements to participate—

• Register with QualityNet, before participating hospitals initially begin

reporting data, regardless of the method used for submitting data.

- Identify a QualityNet Administrator who follows the registration process located on the QualityNet Web site (*http://www.QualityNet.org*).
- Complete a Notice of Participation. New subsection (d) hospitals and existing hospitals that wish to participate in the Hospital IQR Program for the first time must complete an online Notice of Participation (formerly known as "Reporting Hospital Quality Data for Annual Payment Update Notice of Participation," also referred to as IPledge) that includes the name and address of each hospital campus that shares the same CMS Certification Number (CCN). We revise the Notice of Participation periodically as needed and provide appropriate notification of any revisions to hospitals and QIOs through the routine Hospital IQR Program communication channels, which include memo and e-mail notification and QualityNet Web site articles and postings.
- Any hospital that receives a new CCN on or after October 15, 2009 (including new subsection (d) hospitals and hospitals that have merged) that wishes to participate in the Hospital IQR Program and has not otherwise submitted a Notice of Participation using the new CCN must submit a completed Notice of Participation no later than 180 days from the date identified as the open date (that is, the Medicare acceptance date) on the approved CMS Online System Certification and Reporting (OSCAR) system to participate in the Hospital IQR Program. We are proposing regulation text to codify this requirement.
- We will accept Hospital IQR Program withdrawal forms for the FY 2013 payment determination from hospitals any time from October 1, 2011 until August 15, 2012. The August 15, 2012 deadline will give us sufficient time to update the FY 2013 payment to hospitals starting on October 1, 2012. If a hospital withdraws from the program for the FY 2013 payment determination, it will receive a reduction of 2.0 percentage points to the FY 2013 applicable percentage increase. Once a hospital has submitted a Notice of Participation, it is considered to be an active Hospital IQR Program participant until such time as the hospital submits a withdrawal form to CMS.
- We will determine if a hospital has complied with our data submission requirements by looking at whether the hospital has properly submitted data to the appropriate data warehouses for HCAHPS, CDC/NHSN, chart-abstracted measures, and structural measure quality measure data during the four calendar year quarters of FY 2012.

The Hospital IQR Program procedural requirements have remained relatively unchanged for the past several years and we are proposing to codify them at 42 CFR 412.140. We invite public comment on this proposal.

c. Proposed Procedural Requirements for FY 2013 and Subsequent Years

We are proposing that hospitals that have an open date (as noted on the approved CMS OSCAR system) before March 31, 2009 that did not participate in the Hospital IQR Program in FY 2011 or FY 2012 but that wish to participate in the Hospital IQR Program for the FY 2013 payment determination must submit a completed Notice of Participation to CMS on or before December 31, 2011. These hospitals, unlike hospitals that receive a new CCN, do not need to get their operations up and running. Therefore, we believe this is a reasonable deadline that will enable these hospitals to decide whether they want to participate in the Hospital IQR Program while also enabling us to collect enough data from them to make an accurate FY 2013 payment determination. We are proposing regulation text that provides that hospitals that would like to participate in the Hospital IQR program for the first time, or that previously withdrew from the program and would like to participate again, must submit to CMS a completed Notice of Participation Form by December 31 of the fiscal year preceding the fiscal year in which they would like to participate.

d. Proposed Data Submission Requirements for Chart-Abstracted Measures

We are proposing to reduce the quarterly submission deadline for chart-abstracted quality measures from 4½ months to 104 days. In other words, for FY 2014 payment determinations, the quarterly deadline for the quality measures under the topic that require chart abstraction (AMI, HF, PN, SCIP, Emergency Department Throughput (EDT), and Global Immunization (GIM) will be 104 days following the last discharge date in the calendar quarter. We are proposing to reduce the data submission deadline in order to allow for a correction period, which we will propose in future rulemaking. We also believe that this proposed change will encourage hospitals to utilize quality measure information in a more rapid manner to facilitate quality improvement. We also want to provide hospitals sufficient notice of any proposed changes to our submission deadline, since we recognize the advance time needed by hospitals to modify their recordkeeping and abstraction practices to comply with this proposed requirement. We also are proposing to change the aggregate population and sampling deadline from 4 months to 3 months to align with the corresponding proposal to change the data submission deadline from 135 to 104 days.

We will continue to require hospitals to submit aggregate population and sample size counts to CMS on a quarterly basis for Medicare and non-Medicare discharges for the topic areas for which chart-abstracted data must be submitted (currently AMI, HF, PN, and SCIP) (75 FR 50221). Starting with the FY 2014 payment determination, we are proposing to change the submission deadline for hospitals to submit aggregate population and sample size count data for the measures requiring chart abstraction from four months to three months following the last discharge date in the calendar quarter. We are proposing this three-month deadline for submission of the aggregate population and sample size counts data to provide CMS with information necessary to notify hospitals about their data completeness status. Specifically, we currently provide a Provider Participation Report the day after the submitted file is processed, which includes a calculation of the number of hospital submitted cases by topic, hospital self-reported aggregate population and sample size count, and Medicare FFS claims by clinical topic and SCIP surgical category. We expect that hospitals will use this report after submission to assess their patient-level data completeness and will submit additional patient-level cases before the proposed quarterly patient-level deadline. We are proposing to provide hospitals with the same 14-day period after the proposed aggregate population and sample size count deadline to submit the required patient-level records.

e. Proposed Sampling and Case Thresholds Beginning With the FY 2015 Payment Determination

We are proposing to continue the requirement for hospital submission of population and sampling data for the FY 2015 payment determination and future years. Hospitals must submit to CMS quarterly aggregate population and sample size counts for Medicare and non-Medicare discharges for the topic areas for which chart-abstracted data must be submitted (AMI, HF, PN, SCIP, EDT and GIM). Hospitals are required to

submit their aggregate population and sample size count for each topic area.

In accordance with the policy we adopted in the FY 2011 IPPS/LTCH PPS final rule, hospitals that have not treated patients in a specific topic area must still submit quarterly population and sample size counts for all Hospital IQR chart-abstracted data topics. For example, if a hospital has not treated AMI patients, the hospital is still required to submit a zero for its quarterly aggregate population and sample count for that topic in order to meet the requirement. We view it as vital for hospitals to determine accurately their aggregate population and appropriate sampling size data in order for CMS to assess hospitals' data reporting completeness for their total population of cases, Medicare and non-Medicare.

In order to reduce the burden on hospitals that treat a low number of patients in a Hospital IQR Program topic area, a hospital that has five or fewer discharges (Medicare and non-Medicare combined) in a topic area during a quarter in which data must be submitted would not be required to submit patient-level data for that topic area for the quarter. The hospital must still submit its aggregate population and sample size counts for Medicare and non-Medicare discharges for the topic areas each quarter. Hospitals meeting the five or fewer patient discharge exception may voluntarily submit these data.

We strongly recommend that hospitals review the QIO Clinical Warehouse Feedback Reports and the Hospital IQR Program Provider Participation Reports that are available after patient-level data are submitted to the QIO Clinical Warehouse. We generally update these reports on a daily basis to provide accurate information to hospitals about their submissions. These reports enable hospitals to ensure that their data were submitted on time and accepted into the QIO Clinical Warehouse.

f. Proposed HCAHPS Requirements for the FY 2013, FY 2014, and FY 2015 Payment Determinations

Beginning with discharges occurring in third quarter CY 2011, we are proposing to move the HCAHPS data submission deadline forward by one week in order to allow for a review and correction period, which we will propose in future rulemaking. Currently, hospitals have about 14 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse. If this proposal is adopted, hospitals will have about 13 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse.

Other than this proposed change, we are not proposing any other changes to the HCAHPS requirements for the FY 2013 and FY 2014 Hospital IQR Program payment determinations, which were adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220). For FY 2015 Hospital IQR payment determinations, we are proposing to continue the HCAHPS requirements as follows. Under these requirements, a hospital must continuously collect and submit HCAHPS data in accordance with the current HCAHPS *Quality Assurance Guidelines* and the quarterly data submission deadlines, both of which are posted at *http://www.hcahpsonline.org*. In order for a hospital to participate in the collection of HCAHPS data, a hospital must either: (1) Contract with an approved HCAHPS survey vendor that will conduct the survey and submit data on the hospital's behalf to the QIO Clinical Warehouse; or (2) self-administer the survey without using a survey vendor provided that the hospital attends HCAHPS training and meets Minimum Survey Requirements as specified on the HCAHPS Web site at: *http://www.hcahpsonline.org*. A current list of approved HCAHPS survey vendors can be found on the HCAHPS Web site. For the FY 2015 Hospital IQR Program, we are proposing that the HCAHPS data will be based on discharges from January 1, 2013 through December 31, 2013.

Every hospital choosing to contract with a survey vendor must provide the sample frame of HCAHPS-eligible discharges to its survey vendor with sufficient time to allow the survey vendor to begin contacting each sampled patient within 6 weeks of discharge from the hospital. (We refer readers to the *Quality Assurance Guidelines* located at *http://www.hcahpsonline.org* for details about HCAHPS survey administration.) Hospitals are strongly encouraged to submit their entire patient discharge list, excluding patients who had requested "no publicity" status or who are excluded because of State regulations, in a timely manner to their survey vendor to allow adequate time for sample creation, sampling, and survey administration. We wish to emphasize that hospitals must also provide the administrative data that is required for HCAHPS in a timely manner to their survey vendor. This includes the patient MS–DRG at discharge, or alternative information that can be used to determine the patient's service line, in accordance with the survey protocols in the most recent HCAHPS *Quality Assurance Guidelines*.

We note that the HCAHPS *Quality Assurance Guidelines* require that hospitals maintain complete discharge lists that indicate which patients were eligible for the HCAHPS survey, which patients were not eligible, which patients were excluded, and the reason(s) for ineligibility and exclusion. (We refer readers to the *Quality Assurance Guidelines* located at *http://www.hcahpsonline.org* for details about HCAHPS eligibility and sample frame creation.) In addition, the hospital must authorize the survey vendor to submit data via My QualityNet, the secure part of the QualityNet Web site, on the hospital's behalf.

Hospitals must submit at least 300 completed HCAHPS surveys in a rolling four-quarter period unless the hospital is too small to obtain 300 completed surveys. We wish to emphasize that the absence of a sufficient number of HCAHPS eligible discharges is the only acceptable reason for submitting fewer than 300 completed HCAHPS surveys in a rolling four quarter period. If a hospital obtains fewer than 100 completed surveys, the hospital's HCAHPS scores will be accompanied by a footnote on the *Hospital Compare* Web site alerting the Web site users that the scores should be reviewed with caution, as the number of surveys may be too low to reliably assess hospital performance.

After the survey vendor submits the data to the QIO Clinical Warehouse, we strongly recommend that hospitals employing a survey vendor promptly review the two HCAHPS Feedback Reports (the Provider Survey Status Summary Report and the Data Submission Detail Report) that are available. These reports enable a hospital to ensure that its survey vendor has submitted the data on time and the data has been accepted into the QIO Clinical Warehouse.

In order to ensure compliance with HCAHPS survey and administration protocols, hospitals and survey vendors must participate in all oversight activities. As part of the oversight process, during the onsite visits or conference calls, the HCAHPS Project Team will review the hospital's or survey vendor's survey systems and assess protocols based upon the most recent HCAHPS *Quality Assurance Guidelines.* All materials relevant to survey administration will be subject to review. The systems and program review includes, but is not limited to: (a) Survey management and data systems; (b) printing and mailing materials and facilities; (c) telephone

and Interactive Voice Response (IVR) materials and facilities; (d) data receipt, entry and storage facilities; and, (e) written documentation of survey processes. As needed, hospitals and survey vendors will be subject to follow-up site visits or conference calls. We wish to point out that the HCAHPS *Quality Assurance Guidelines* state that hospitals should refrain from activities that explicitly influence how patients respond on the HCAHPS survey. If we determine that a hospital is not compliant with HCAHPS program requirements, we may determine that the hospital is not submitting HCAHPS data that meet the requirements of the Hospital IQR Program.

We continue to strongly recommend that each new hospital participate in an HCAHPS dry run, if feasible, prior to beginning to collect HCAHPS data on an ongoing basis to meet Hospital IQR Program requirements. New hospitals can conduct a dry run in the last month of a calendar quarter. The dry run will give newly participating hospitals the opportunity to gain first-hand experience collecting and transmitting HCAHPS data without the public reporting of results. Using the official survey instrument and the approved modes of administration and data collection protocols, hospitals/survey vendors will collect HCAHPS dry-run data and submit the data to My QualityNet, the secure portion of QualityNet.

We again are encouraging hospitals to regularly check the HCAHPS Web site at *http://www.hcahpsonline.org* for program updates and information.

We proposed that HCAHPS scores become part of the Hospital VBP Program in FY 2013. As HCAHPS scores become incorporated in hospital payment, we believe that a neutral third-party should administer the survey for hospitals whose annual payment updates will be affected by their HCAHPS scores. It is our belief that an experienced survey vendor will be best able to ensure reliable results. Therefore, we are considering whether to allow only non-subsection (d) hospitals to self-administer the HCAHPS survey. We invite public comment that will inform our future policy on this issue.

g. Proposed Procedures for Claims-Based Measures

CMS is proposing to adopt a new claims-based measure for FY 2014, the Medicare Spending per Beneficiary Measure, which is included in the chart below.

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Topic	FY 2014 Payment Determination: Adopted and Proposed Claims-Based Quality Measures (No Additional Hospital Data Submission Required)
Mortality Measures (Medicare Patients)	
	• Acute Myocardial Infarction (AMI) 30-day mortality rate
	• Heart Failure (HF) 30-day mortality rate
	• Pneumonia (PN) 30-day mortality rate
Complications	
Readmission Measure (Medicare Patients)	
	• Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure
	• Heart Failure 30-day Risk Standardized Readmission Measure
	• Pneumonia 30-day Risk Standardized Readmission Measure
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures	
	• PSI 06: Iatrogenic pneumothorax, adult
	• PSI 11: Post Operative Respiratory Failure
	• PSI 12: Post Operative PE or DVT
	• PSI 14: Postoperative wound dehiscence
	• PSI 15: Accidental puncture or laceration
	• IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume)
	• IQI 19: Hip fracture mortality rate
	• Complication/patient safety for selected indicators (composite)
	• Mortality for selected medical conditions (composite)
AHRQ PSI and Nursing Sensitive Care	
	• PSI 04 Death among surgical inpatients with serious treatable complications
Hospital Acquired Condition Measures	
	• Foreign Object Retained After Surgery
	• Air Embolism
	• Blood Incompatibility
	• Pressure Ulcer Stages III & IV
	• Falls and Trauma: (Includes: Fracture Dislocation Intracranial Injury Crushing Injury Burn Electric Shock)
	• Vascular Catheter-Associated Infection
	• Catheter-Associated Urinary Tract Infection (UTI)
	• Manifestations of Poor Glycemic Control
Cost Efficiency	
	• Medicare Spending per Beneficiary*

*New proposed measure for FY 2014

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We are not proposing to change the procedures and time periods we adopted in the FY 2011 IPPS/LTCH PPS final rule for the FY 2012, FY 2013 and FY 2014 payment determinations. For the FY 2014 payment determination, we are proposing to use up to 3 years of Medicare FFS claims data to calculate the measures, as appropriate for the measure.

Hospitals are encouraged to regularly check the QualityNet Web site, *http://www.QualityNet.org,* for program updates and information.

h. Proposed Data Submission Requirements for Structural Measures

Structural measures assess the characteristics and capacity of the provider to deliver quality healthcare. We are proposing to add one additional structural measure for the FY 2014 payment determination, Participation in a Systematic Clinical Database Registry for General Surgery, and to align the submission deadline for all structural measures with the submission deadline for the fourth quarter of the chart-abstracted measures. We are proposing to update the period of data collection that hospitals will submit the required registry participation information once annually for the structural measures via a Web-based collection tool between April 1, 2012 and May 15, 2012 with respect to the time period of January 1, 2011 through December 31, 2011. This proposal will give CMS a more complete picture of registry participation as well as synchronize data submissions for structural and chart-abstracted measures. These measures do not require the hospital to participate in a registry.

Below is the list of structural measures we have adopted or are proposing to adopt for the FY 2014 payment determination:

Topic	FY 2014 Payment Determination: Adopted and Proposed Structural Measures
Cardiac Surgery	
	• Participation in a Systematic Database for Cardiac Surgery
Stroke Care	
	• Participation in a Systematic Clinical Database Registry for Stroke Care
Nursing Sensitive Care	
	• Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care
General Surgery	
	• Participation in a Systematic Clinical Database Registry for General Surgery*

*New proposed measures for FY 2014

i. Proposed Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

As discussed above, we are proposing to adopt 2 new HAI measures for the FY 2014 payment determination and 3 HAI measures for FY 2015 payment determination. For FY 2014, the two proposed measures are Central Line Insertion Practices Adherence Percentage and Catheter Associated Urinary Tract Infection. For FY 2015, the three proposed measures are: Healthcare Provider Influenza Vaccination, MRSA Bacterimia and C. Difficile. Below is the list of HAI measures we are proposing to adopt for the FY 2014 and FY 2015 payment determinations:

Topic	FY 2014 and 2015 Payment Determination: Proposed and Adopted Healthcare-Associated Infection Measures (CDC/NHSN)
	Surgical Site Infection*
	Central Line Insertion Practices Adherence Percentage**
	Catheter Associated Urinary Tract Infection**
	Clostridium Difficile***
	Healthcare Provider Influenza Vaccination***
	MRSA Bacteremia***

* Measures adopted for FY 2014 payment determination in the FY 2011 IPPS/LTCH PPS final rule

** Measures proposed for FY 2014 payment determination in this proposed rule

*** Measures proposed for FY 2015 payment determination in this proposed rule

We are proposing to update the current data submission and reporting requirements for these proposed measures. Specifically, we are proposing to utilize the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of these measures to NHSN. We refer readers to the CDC's NHSN Web site (*http://www.cdc.gov/nhsn*) for detailed data submission and reporting procedures. We believe that these procedures are feasible because they are already widely used by over 4,000 hospitals reporting HAI data using the NHSN. Our proposal seeks to reduce hospital burden by aligning CMS data submission and reporting procedures with NHSN procedures currently utilized by hospitals, including hospitals complying with 28 State HAI reporting requirements. The existing data collection and submission timeframes for the HAI measures for the FY 2014 payment determination, which we are proposing to use for the HAI measures we have proposed above, are shown below. Hospitals must submit their quarterly data to NHSN for Hospital IQR Program purposes on or around the dates shown in the table below (updates to this will be posted on the QualityNet Web site).

Submission Timeframes for HAI Measures for the FY 2014 Payment Determination

CY 2012 Infection Events, and Central Line Insertion Practices	CDC-NHSN Collection and Quarterly Report Generation Timeframe	Final Submission Deadline for Hospital IQR Program FY 2014 Payment Determination
Q1 (Jan-Mar 2012)	January 31st – August 15th	August 15, 2012
Q2 (Apr-Jun 2012)	April 30th – November 15th	November 15, 2012
Q3 (Jul-Sep 2012)	July 31st – Feb-15th	February 15, 2013
Q4 (Oct-Dec 2012)	October 31st – May 15th	May 15, 2013

Hospitals would have until the Hospital IQR Program final submission deadline to submit their quarterly data to NHSN. After the final Hospital IQR Program submission deadline has occurred for each CY 2012 quarter, CMS will obtain the hospital-specific calculations that have been generated by the NHSN for the Hospital IQR Program.

We invite public comment on this proposal.

6. Proposed Chart Validation Requirements for Chart-Abstracted Measures

a. Proposed Changes to the Chart Validation Requirements and Methods for the FY 2012 Payment Determination and Subsequent Years

We are proposing several changes to the chart validation requirements and methods we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225 through 50229) for the FY 2012 payment determination and subsequent years. In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45 days from the date of the request to submit the requested records. If any record(s) were not received by the 45-day requirement, the CMS CDAC contractor assigned a "zero" validation score to each measure in a missing record. We are proposing to change the time period given to hospitals to submit medical records to the CDAC contractor to 30 calendar days, and we are proposing to codify this proposal at 42 CFR 412.140(d)(1). This proposed change in submission timeframe will align the current process with the requirements in 42 CFR 476.78(b)(2), which currently allow only 30 days for chart submission in the context of reviews by QIOs. We are proposing this deadline modification to reduce the time we need to complete validation, and provide hospitals with feedback on their abstraction accuracy. We believe that this linkage between Hospital IQR Program validation discharge quarters and the same fiscal year's Hospital VBP Program proposed performance period would improve the reliability and accuracy of the Hospital VBP Program's chart-abstracted measures. Hospitals that are subject to Hospital IQR payment reduction due to not passing our validation requirement would be excluded from receiving a Hospital VBP performance score and corresponding incentive payment under section 1886(o)(1)(C)(ii)(I) of the Act. Thus, CMS would ensure that the data submitted on chart-abstracted measures we adopt for the Hospital VBP Program is accurate by virtue of validating it under the validation procedures we have adopted for the Hospital IQR Program.

b. Proposed Supplements to the Chart Validation Process for the FY 2014 Payment Determination and Subsequent Years

We are proposing to continue to use the supplements to the chart validation requirements and methods we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227 through 50229) for FY 2014 payment determinations and future years with several proposed modifications.

We are proposing to add hospitals to our validation sample if they were open under their current CCNs in FY 2012 but not selected for validation in the three previous annual Hospital IQR Program validation samples. We are proposing this addition to supplement

our validation approach to ensure that all eligible Hospital IQR Program hospitals are selected for validation at least once every 4 years. We are proposing this addition starting in FY 2015 because FY 2015 would be the fourth year that CMS would have used the random validation approach (which begins in FY 2012 as adopted in the FY 2011 IPPS/LTCH PPS final rule). We invite public comment on this proposal.

We believe that this proposed Hospital IQR Program validation process meets the requirements set forth in section 1886(b)(3)(B)(viii)(XI) of the Act. This section states that "the Secretary shall establish a process to validate measures specified under this clause as appropriate. Such process shall include the auditing of a number of randomly selected hospitals sufficient to ensure validity of the reporting program under this clause as a whole and shall provide a hospital with an opportunity to appeal the validation of measures reported by such hospital."

Starting with the FY 2012 payment determination and continuing in subsequent fiscal years, the chart validation process audits 800 randomly selected hospitals for the discharge quarters. This sample size is sufficient to validate more than 22 percent of subsection (d) hospitals in an applicable fiscal year and ensure accuracy of the Hospital IQR Program quality data.

For FY 2014 payment determination, we are proposing to validate 24 chart-abstracted measures including 19 currently validated measures, and 5 proposed additional measures. The FY 2014 proposed validation reflects the 5 measures we are proposing to add (2 EDT measures, Central Line Associated Blood Stream Infection, Global Influenza Immunization, and Global Pneumonia Immunization measures) and the 8 measures we are proposing to retire (AMI–1, AMI–3, AMI–4, AMI–5, HF–4, PN–4, PN–5c, and SCIP Infection 6).

Validation of the HCAHPS measure is conducted through our oversight activities. We provide oversight of all HCAHPS survey vendors and hospitals self-administering the survey in order to ensure that the data collection protocols are followed. We also provide oversight and validation through our review of Quality Assurance Plans, site visits, conference calls and detailed data analyses each quarter to ensure there are no anomalies found in the data. In particular, we use site visits to review all data collection activities, including data reviews to track a discharged patient from sampling to survey administration to data submission.

We are proposing, starting with FY 2014 payment determinations, a modest increase to the current Hospital IQR Program validation sample of SCIP, AMI, HF, and PN cases. Specifically, we are proposing to add three charts per selected hospital per quarter to the validation sample. This additional quarterly sample would enable us to validate the CLABSI measure that we added to the Hospital IQR Program measure set beginning with the FY 2014 payment determination. CLABSI is a relatively rare event compared to SCIP, AMI, HF, and PN cases. In 2009, about 18,000 CLABSIs occurred in ICU patients in the United States, and these infections were a major contributor to prolonged hospital stays and inpatient mortality. We are proposing a process to validate the CLABSI measure that takes into account the relative infrequency of this event and the case-finding methodology for it, specifically the requirements for a positive blood culture result and the presence of a central venous catheter in the patient at the time of, or within 48 hours before, onset of the infection. We recognize that the current validation process and sample size for AMI, HF, PN, and SCIP measures is not likely to be sufficiently reliable to detect systematic underreporting of CLABSI. Unlike the current AMI, HF, PN, and SCIP chart abstracted process of care measures, CLABSI is a rarely occurring infection among acute care inpatient discharges. We estimate that between 0.1 percent to 0.2 percent of all acute care inpatient patient discharges nationwide involve patients who are infected with a CLABSI. We believe that our current Hospital IQR AMI, HF, PN, and SCIP sample sizes and sample methods would not reliably validate CLABSI measure rates at the hospital level because of the relatively rare occurrence of these events. We also seek to target validation of the CLABSI measure to minimize hospital burden in complying with our sample size proposals, for which hospitals must find, photocopy, and return requested medical records to CMS. If CMS did not utilize this targeted validation approach for the CLABSI measure, hospitals would have to submit 200 to 300 additional randomly selected cases in order to effectively validate this measure, given its rare occurrence. We believe that our proposed CLABSI validation process addresses these limitations through the use of a targeted incremental validation sample comprised of three charts of possible CLABSI events, and will reliably validate the Hospital IQR Program CLABSI measure while not overly burdening hospitals with medical record requests.

Specifically, we are proposing to identify sampled hospitals' three quarterly potential CLABSI charts using a two-step selection process that would target intensive care unit patients with bloodstream infection (positive blood culture results) and a Central Venous Catheter (CVC) provided by sampled hospitals to CMS. In the first step of this process, a CMS contractor would require the 800 randomly sampled hospitals to provide a quarterly list of all blood cultures positive for infection status taken from intensive care units conducting CLABSI surveillance during the discharge quarter. We are aware that this list will include both reported CLABSI events and many non-CLABSI events, including patients with and without CVCs. In clinical terms, our intent in reviewing these positive blood culture lists is to identify the information needed to determine whether the blood culture isolate is a likely pathogen found at least once, or a common skin commensal (CSC) found in two or more positive blood cultures drawn on separate occasions. CSC's are microorganisms that are commonly found on the skin and often indicate contamination of the blood culture media rather than infection by the microorganism when it is identified in a single blood culture test. Two sets of blood cultures are needed to differentiate true infection from contamination. The list of CSCs is comprised of the following organisms: diphtheroids (*Corynebacterium* spp.); *Bacillus* spp. (not *B. anthracis*); *Priopionibacterium* spp.; coagulase negative staphylococci including *S. epidermidis;* viridans group streptococci; *Aerococcus* spp.; and *Micrococcus* spp. This list of CSCs is also found at the NHSN Web site, *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.* We would also require hospitals to self-identify intensive care unit patients with a CVC that are on this blood culture list. Using all of this information, we would be able to identify intensive care unit patients with a bloodstream infection and with a CVC (that is, candidate CLABSI events) for subsequent sampling.

In the second step of this process, we would randomly sample these candidate CLABSI events (ICU patients with a CVC and where a pathogen was recovered at least once or the same CSC was cultured from 2 or more blood cultures drawn on separate occasions). Specifically, the CMS CDAC would require hospitals to submit up to 3 medical records each quarter meeting

these criteria, randomly selected by CMS from among eligible charts. This number of medical records is sufficient to detect unreported CLABSI events based on our sample size analysis and experience from State health department validation efforts. This proposed process utilizes the validation experience from at least ten current State health department validation initiatives. In addition, we are proposing to randomly validate CLABSI data by abstracting all necessary quality data from the 12 quarterly medical records in our AMI, HF, PN, and SCIP targets already collected for IQR validation as well as the 3 additional records we later propose to collect for ED throughput/Immunization. Our intent in validating all currently requested quarterly medical records for CLABSI is to assess reliability of CLABSI measure rates from a random sample of patients independent from the proposed 3 record sample selected using blood culture lists and CVC presence to target underreporting of CLABSI events to the CDC's NHSN. In our proposed 12 record random sample of CLABSI events, we will not use blood culture list and CVC presence in our sampling, since this sample is already drawn from the AMI, HF, PN, and SCIP hospital reported data reported to CMS. By combining a random and targeted sampling approach using two independent sources to validate CLABSI data, we believe that we are adequately assessing the accuracy and reliability of the CLABSI measure in accordance with section 1886(b)(3)(B)(viii)(XI) of the Act.

We are proposing to determine the CLABSI validation score using a process that begins with the CMS contractor validation coordinator comparing the CDAC's CLABSI infection status to the hospital's event data reported to NHSN for the applicable quarter. For each medical record reviewed, a hospital would receive a match only if the CMS contractor validation coordinator determines equivalency between the CMS contractor's determination of infection status and the infection status reported to NHSN. For example, if one of the CMS-requested validation medical records revealed CLABSI and the event was not reported to the NHSN, then the hospital would receive a zero score for the CLABSI measure for that validated record. If the CMS contractor discovered that a second record in the CMS validation sample indicated no CLABSI event, but a CLABSI was reported to the NHSN for the record, the hospital would also receive a zero score for the CLABSI measure for that validation record. Thus, Hospitals would only receive a 100% CLABSI validation score for individual records if their CMS validation records' CLABSI status was consistent with the information reported, or not reported, to NHSN. In the above example, if the CMS quarterly validation process identified that 13 out of 15 total sampled records accurately reported the presence of a CLABSI or did not report a CLABSI where none was present, then the hospital's CLABSI validation score would be 13⁄15, or about 87 percent.

Starting with FY 2014 payment determination, we are also proposing to add a sixth quarterly sample, which would enable us to validate the EDT measures and the Immunization for Influenza and Immunization for Pneumonia global measures that we added to the Hospital IQR Program measure set. We are proposing to modify the current process (75 FR 50225–75 FR 50229) for these measures in two ways. First, we are proposing to select 3 additional records each quarter from the records submitted by the 800 annually sampled hospitals. These records would only include principal diagnoses and surgical procedures not already included in the AMI, HF, PN, and SCIP populations eligible for validation sampling in these four topic areas. Second, we would abstract EDT and the Immunization for Influenza and Immunization for Pneumonia global measure data from the 15 quarterly AMI, HF, PN, SCIP and CLABSI records already submitted by hospitals for IQR validation. We would validate 18 records per quarter for these measures. With the addition of this sample of three records, we would ensure that all hospitals that reported chart-abstracted Hospital IQR data in all principal procedure and diagnosis codes would be eligible for sample selection for these global measures, thus, starting in FY 2014, we would be validating a total of 18 records per quarter per validated hospital in 6 strata (1) SCIP, (2) AMI, (3) HF, (4) PN, (5) CLABSI, and (6) EDT/immunization measures.

7. Proposed QIO Regulation Changes for Provider Medical Record Deadlines Possibly Including Serious Reportable Events

Our Hospital IQR validation requirement has utilized 42 CFR 476.78 authority and deadlines to require participating hospitals to return requested medical record information in a timely manner. Our State QIOs use this information to educate hospitals on medical record abstraction accuracy, and identify potential opportunities for quality improvement through medical record review. It is our goal to improve the alignment of QIO work in the Hospital IQR Program, quality improvement assistance, beneficiary (or beneficiary representative) requested QIO quality of care reviews, and QIO medical necessity reviews to improve the following three aims: (1) Improve individual care; (2) improve health for populations; and (3) lower cost through improvement. QIOs serve a critical role in advancing these three aims through their work with Medicare providers and beneficiaries to advance quality care and health.

Moreover, because we developed our validation process based on the requirements of the QIO program regulations, we are also proposing corresponding changes to 42 CFR 476.78(b), along with minor editorial revisions. This section includes requirements related to the submission of medical information as well as other information associated with the prospective payment system. Specifically, we are proposing to add a new § 478.78(b)(2)(ii) that would require the submission of medical information within 21 days in those situations in which a "serious reportable event" or other circumstance has been identified during the course of a QIO review. For purposes of this subsection, we are proposing to define the term "serious reportable event" to be consistent with the NQF's definition of a serious reportable event in its report "Serious Reportable Events in Healthcare 2006 Update." These events include the following:

Surgical Events

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately postoperative death in an ASA Class I patient

Product or Device Events

- Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility
- Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
- Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

Patient Protection Events

- Infant discharged to the wrong person
- Patient death or serious disability associated with patient leaving the facility without permission
- Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility

Care Management Events

- Patient death or serious disability associated with a medication error (for example, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)
- Patient death or serious disability associated with a hemolytic reaction (abnormal breakdown of red blood cells) due to the administration of ABO/HLA—incompatible blood or blood products
- Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
- Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- Death or serious disability associated with failure to identify and treat hyperbilirubinemia (condition where there is a high amount of bilirubin in the blood) in newborns
- Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- Patient death or serious disability due to spinal manipulative therapy
- Artificial insemination with the wrong donor sperm or wrong egg

Environmental Events

- Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
- Patient death or serious disability associated with a fall while being cared for in a healthcare facility
- Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

Criminal Events

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient of any age
- Sexual assault on a patient within or on the grounds of a healthcare facility
- Death or significant injury of a patient or staff member resulting from a physical assault (that is, battery) that occurs within or on the grounds of a healthcare facility

This proposed 21 day medical record deadline would be used when, for example, in the QIO's judgment, delays in receiving medical information could negatively undermine its efforts to evaluate the quality of care provided or the facility's adherence to payment policies. It also would enable QIOs to better utilize, and respond to, information about adverse events gained from the quality reporting program, in a timely fashion so that QIOs can have an improved and more immediate impact on the quality of health care.

We also are proposing a technical correction to 42 CFR 476.78(a) to correct a cross reference.

We invite public comment on our proposal to improve patient care through QIO access to more rapid provider information about "serious reportable events" and our proposed technical correction to 42 CFR 476.78(a).

8. Proposed Data Accuracy and Completeness Acknowledgement Requirements for the FY 2012 Payment Determination and Subsequent Years

We are proposing to require hospitals to continue to electronically acknowledge their data accuracy and completeness once annually. However, we are proposing to change the submission deadline to be used for the FY 2012 Hospital IQR Program payment determination and subsequent years. This proposal will allow us to align the submission deadline with the final quarter of the chart-abstracted measures. Hospitals will continue to submit the required electronic acknowledgment attesting that the data provided to meet the FY 2012 Hospital IQR Program data submission requirements is accurate and complete to the best of the hospital's knowledge at the time of data submission. We are proposing to make the submission deadline for the Data Accuracy and Completeness Acknowledgement May 15, 2012 with respect to the time period of January 1, 2011 through December 31, 2011. We invite public comment on this proposal.

9. Proposed Public Display Requirements for the FY 2014 Payment Determination and Subsequent Years

We are proposing to continue, for the FY 2014 payment determination and subsequent years, the approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) for public display requirements for the FY 2012 payment determination and subsequent years.

The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* Web site *http://www.hospitalcompare.hhs.gov,* but on occasion are reported on other CMS Web sites. We require that hospitals sign a Notice of Participation form when they first register to participate in the Hospital IQR Program. Once a hospital has submitted a form, the hospital is considered to be an active Hospital IQR Program participant until such time as the hospital submits a withdrawal form to CMS (72 FR 47360). Hospitals signing this form agree that they will allow us to publicly report the quality measures included in the Hospital IQR Program.

We will continue to display quality information for public viewing as required by section 1886(b)(3)(B)(viii)(VII) of the Act. Before we display this information, hospitals will be permitted to review their information as recorded in the QIO Clinical Warehouse.

We invite public comment on this proposal.

10. Proposed Reconsideration and Appeal Procedures for the FY 2012 Payment Determination

We are proposing to continue, for the FY 2012 payment determination and subsequent years, the general approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) for reconsideration and appeal procedures for the FY 2011 payment determination. We also are proposing to codify the requirements under this process at 42 CFR 412.140(e). We discuss each of the regulatory provisions being proposed, as well as specific changes, below.

We are proposing that the general deadline for submitting a request for reconsideration in connection with the FY 2012 payment determination will be 30 days from the date of receipt of the payment determination notification. Historically, most reconsideration requests are based on the failure to meet established data submission deadlines. While we want to ensure that hospitals have an opportunity to request reconsiderations when warranted, we also need to balance this goal with our need to complete the reconsideration

process in a timely manner and with the hospitals' desire to obtain final decisions on their requests in a timely manner. Therefore, we are proposing to reduce the reconsideration and appeal period from a deadline of November 1st 2012 to 30 days after hospital receipt of the payment determination notification. Notifications will be sent via a trackable mail option such as Certified U.S. Mail or Registered Mail. We include this change in the proposed § 412.140(e)(1).

As discussed more fully below, we are proposing that all hospitals submit a request for reconsideration and receive a decision on that request before they can file an appeal with the Provider Reimbursement Review Board (PRRB). For the FY 2012 payment determination, we are proposing to continue utilizing many of the same procedures that we utilized for the FY 2011 requests for reconsideration. We are, however, clarifying that a hospital must submit all documentation and evidence that supports its request for reconsideration at the time that it submits its request. This includes copies of any communications, such as e-mails that the hospital believes demonstrate its compliance with the program requirements, as well as all paper medical records that support the hospital's rationale for seeking reconsideration. The information that must be included when a hospital submits a reconsideration request has been listed in proposed § 412.140(e)(2). Under these proposed procedures, the hospital must:

—Submit to CMS, via *QualityNet,* a Reconsideration Request form (available on the *QualityNet* Web site) containing the following information:
—Hospital CMS Certification number (CCN).
—Hospital Name.
—CMS-identified reason for failure (as provided in the CMS notification of failure letter to the hospital).
—Hospital basis for requesting reconsideration. This must identify the hospital's specific reason(s) for believing it met the Hospital IQR Program requirements and should receive the full update to the standardized amount.
—CEO contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box). We note that to the extent a hospital can submit a request for reconsideration on-line, the burden on our staff would be reduced and, as a result, we can more quickly review the request.
—QualityNet System Administrator contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box).
—Paper medical record requirement for reconsideration requests involving validation. We are proposing that if a hospital asks us to reconsider an adverse Hospital IQR Program payment decision made because the hospital failed the validation requirement, the hospital must submit paper copies of all the medical records that it submitted to the CDAC contractor each quarter for purposes of the validation. Hospitals must submit this documentation to a CMS contractor. The contractor will be a QIO support contractor, which has authority to review patient level information under 42 CFR part 480. We will post the address where hospitals can ship the paper charts on the QualityNet Web site after we issue the FY 2012 IPPS/LTCH PPS final rule.

Hospitals submitting a Hospital IQR Program validation reconsideration request will have all data elements to be reconsidered reviewed by CMS, and not their State QIO. (The State QIO is available to conduct a quarterly validation appeal if requested to do so by a hospital.)

Hospitals must provide a written justification for each appealed data element classified during the validation process as a mismatch. We will review the data elements that were labeled as mismatched, as well as the written justifications provided by the hospitals, and make a decision on the reconsideration request.

As we mentioned above, hospitals that submit a reconsideration request to CMS must receive a decision on that request prior to submitting a PRRB appeal. We believe that the reconsideration process is less costly for both CMS and hospitals, and that it decreases the number of PRRB appeals by resolving issues earlier in the reconsideration and appeals process. We have proposed language at § 412.140(e)(3) stating that a hospital that receives an adverse decision on its reconsideration request may appeal that decision to the PRRB.

Following receipt of a request for reconsideration, we will—

- Provide an e-mail acknowledgement, using the contact information provided in the reconsideration request, to the CEO and the QualityNet Administrator that the request has been received.
- Provide written notification to the hospital CEO, using the contact information provided in the reconsideration request, regarding our decision. We expect the process to take approximately 90 days from the receipt of the reconsideration request.

We are proposing to continue for the FY 2012 Hospital IQR reconsideration and future years the scope of review when a hospital requests reconsideration because it failed our validation requirements, which we adopted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43892). The scope of this review will be as follows:

1. *Hospital requests reconsideration for CDAC contractor-abstracted data elements classified as mismatches affecting validation scores.* Hospitals must timely submit a copy of the entire requested medical record to the CDAC contractor during the quarterly validation process for the requested case to be eligible to be reconsidered on the basis of mismatched data elements. Only hospitals that fail to meet the passing threshold for the quarterly validation would receive an opportunity to appeal the validation results to their State QIO.

2. *Hospital requests reconsideration for medical record copies submitted during the quarterly validation process and classified as invalid record selections.* Invalid record selections are defined as medical records submitted by hospitals during the quarterly validation process that do not match the patient's episode of care information as determined by the CDAC contractor (in other words, the contractor determines that the hospital returned a medical record that is different from that which was requested). If the CDAC contractor determines that the hospital has submitted an invalid record selection case, it awards a zero validation score for the case because the hospital did not submit the entire copy of the medical record for that requested case. During the reconsideration process, our review of invalid record selections will initially be limited to determining whether the record submitted to the CDAC contractor was actually an entire copy of the requested medical record. If we determine during reconsideration that the hospital did submit the entire copy of the requested medical record, then we would abstract data elements from the medical record submitted by the hospital.

3. *Hospital requests reconsideration for medical records not submitted to the CDAC contractor within the proposed 30 calendar day deadline.* Our review will initially be limited to determining whether the CDAC contractor received the requested record within the proposed 30 calendar days, and whether

the hospital received the initial medical record request. If we determine during reconsideration that the CDAC contractor did receive a paper copy of the requested medical record within the proposed 30 calendar days, then we would abstract data elements from the medical record submitted by the hospital. If we determine that the hospital received a request for medical records and did not submit the requested records within the proposed 30 day period, CMS will not accept these records as part of the reconsideration. CMS will not abstract data from charts not received timely by the CMS contractor. Please note that this proposed language is also designed to address those instances where the hospital's request is based on "invalid record selections," which we have defined as medical records submitted during the quarterly validation process that do not match the patient's episode of care information as determined by the CMS contractor as described above in situation 2, above "Hospital requests reconsideration for medical record copies submitted during the quarterly validation process and classified as invalid record selections."

In sum, we are proposing to continue to initially limit the scope of our reconsideration reviews involving validation to information already submitted by the hospital during the quarterly validation process, and we will not abstract medical records that were not submitted to the CMS contractor during the quarterly validation process. We would expand the scope of our review only if we find during the initial review that the hospital correctly and timely submitted the requested medical records. In that case, we would abstract data elements from the medical record submitted by the hospital as part of our review of its reconsideration request.

If a hospital is dissatisfied with the result of a Hospital IQR Program reconsideration decision, the hospital may file an appeal under 42 CFR Part 405, Subpart R (a PRRB appeal). We invite public comment on the extent to which these proposed procedures will be less costly for hospitals, and whether they will lead to fewer PRRB appeals.

11. Proposed Hospital IQR Program Disaster Waivers

In our experience, there have been times when hospitals have been unable to submit required quality data due to extraordinary circumstances that are not within their control. It is our goal to not penalize hospitals for such circumstances or unduly increase their burden during these times. Therefore, we are proposing to continue, for the FY 2014 and subsequent years payment determinations, the process we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225), for hospitals to request and for CMS to grant waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the hospital. Under the process, in the event of extraordinary circumstances, such as a natural disaster, not within the control of the hospital, for the hospital to receive consideration for an extension or waiver of the requirement to submit quality data for one or more quarters, a hospital would submit to CMS a request form that would be made available on the QualityNet Web site. The following information should be noted on the form:

- Hospital CCN;
- Hospital Name;
- CEO and any other designated personnel contact information, including name, e-mail address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);
- Hospital's reason for requesting an extension or waiver;
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the hospital will again be able to submit Hospital IQR Program data, and a justification for the proposed date.

The request form must be signed by the hospital's CEO. We are proposing that a request form must be submitted within 30, rather than 45, days of the date that the extraordinary circumstance occurred. The QIO in the hospital's state will forward the request form to CMS. Following receipt of the request form, CMS will: (1) provide a written acknowledgement using the contact information provided in the request, to the CEO and any additional designated hospital personnel, notifying them that the hospital's request has been received; and (2) provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of our decision.

This proposal does not preclude CMS from granting waivers or extensions to hospitals that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane), affects an entire region or locale. If CMS makes the determination to grant a waiver or extension to hospitals in a region or locale, CMS proposes to communicate this decision through routine communication channels to hospitals, vendors and QIOs, including but not limited to issuing memos, e-mails and notices on the QualityNet Web site. We are proposing to include an overview of this process in proposed 42 CFR 412.140(c)(2). We invite public comment on this proposal.

12. Electronic Health Records (EHRs)

a. Background

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of EHRs (also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from the EHRs directly to a CMS data repository (70 FR 47420 through 47421). We sought to prepare for future EHR submission of quality measures by sponsoring the creation of electronic specifications for quality measures under consideration for the Hospital IQR Program.

b. HITECH Act EHR Provisions

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes payment incentives under Medicare for the adoption and use of certified EHR technology beginning in FY 2011. Hospitals are eligible for these payment incentives if they meet requirements for meaningful use of certified EHR technology, which include reporting on quality measures using certified EHR technology. With respect to the selection of quality measures for this purpose, under section 1886(n)(3)(A)(iii) of the Act, as added by section 4102 of the HITECH Act, the Secretary shall select measures, including clinical quality measures, that hospitals must provide to CMS in order to be eligible for the EHR incentive payments. With respect to the clinical quality measures, section 1886(n)(3)(B)(i) of the Act requires the Secretary to give preference to those clinical quality measures that have been selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. All measures must be proposed for public comment prior to their selection, except in the case of measures previously selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act. The final rule for the Medicare and Medicaid EHR Incentive Programs includes 15 clinical quality measures for eligible hospitals and critical access hospitals (75 FR 44418), 2 of which were previously

selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act. The remainder of the measures for these incentive programs are being proposed for the Hospital IQR Program for the FY 2015 payment determination.

We continue to believe there are important synergies with respect to the two programs. We believe the financial incentives under the HITECH Act for the adoption and meaningful use of certified EHR technology by hospitals will encourage the adoption and use of certified EHRs for the reporting of clinical quality measures under the Hospital IQR Program. Through the EHR Incentive Programs we expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS to receive, quality measures via hospital EHRs for Hospital IQR Program measures in the future.

The HITECH Act requires that the Secretary seek to avoid redundant and duplicative reporting, with specific reference to the Hospital IQR Program for eligible hospitals. To the extent that quality measures are included in both the Hospital IQR Program and the EHR Incentive Programs, this would mean that Hospital IQR Program would need to transition to use of certified EHR technology rather than manual chart abstraction. We are considering what the most practical approach to effect such a transition might be. One option is to select a date after which chart-abstracted data would no longer be used in the Hospital IQR Program. This would require sufficient advance notice to hospitals for hospitals to report the data via certified EHR technology. At that point, we believe that it is likely that nearly all IPPS hospitals will have implemented certified EHR technology as incentivized by the HITECH Act. Another option would be to allow hospitals to submit the same measure for the Hospital IQR Program based on either chart-abstraction or EHR-based reporting. This would require extensive testing to ensure equivalence given that the data for the Hospital IQR Program supports both the public reporting of such information and the Hospital VBP Program. We are concerned that this option would not be feasible. We invite public comment on the approach of selecting a date such as calendar year 2015 after which chart-abstracted data would no longer be accepted for the Hospital IQR Program.

Ultimately, we do not anticipate having two different sets of clinical quality measures for the EHR Incentive Program and the Hospital IQR Program. Rather, we anticipate a single set of hospital clinical quality measures, most of which we anticipate would be electronically specified. We envision a single reporting infrastructure for electronic submission in the future, and will strive to align the hospital quality initiative programs to seek to avoid redundant and duplicative reporting of quality measures for hospitals. We note that some important Hospital IQR Program quality measures such as HCAHPS experience of care measures are based on survey data and do not lend themselves to EHR reporting. Similarly, certain outcome quality measures, such as the current Hospital IQR Program readmission measures, are based on claims rather than clinical data. Thus, not all Hospital IRP quality measures will necessarily be capable of being submitted through EHRs. As a consequence, not all Hospital IQR Program measures would necessarily be appropriate for inclusion in the EHR Incentive Programs.

We again note that the provisions in this FY 2012 IPPS/LTCH PPS proposed rule do not implicate or implement any HITECH statutory provisions. Those provisions are the subject of separate rulemaking and public comment.

B. Hospital Value-Based Purchasing (VBP) Program

1. Background

Section 1886(o) of the Act requires the Secretary to establish a Hospital Inpatient VBP Program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital Inpatient VBP Program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to the FY 2013 base operating MS–DRG payment for each discharge of 1 percent, as required by section 1886(o)(7)(B)(i) of the Act.

Section 1886(o)(1)(C) of the Act provides that the Hospital Inpatient VBP Program applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term "hospital," with respect to a fiscal year: (1) A hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program) for such fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary cited deficiencies that pose immediate jeopardy to the health or safety of patients; and (3) a hospital for which there are not a minimum number (as determined by the Secretary) of measures for the performance period for the fiscal year involved, or for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

2. Overview of the Hospital Inpatient VBP Program Proposed Rule

On January 7, 2011, we issued the Hospital Inpatient VBP Program proposed rule to implement section 1886(o) of the Act (76 FR 2454 through 2491). This proposed rule was developed based on extensive research we conducted on hospital value-based purchasing, including research that formed the basis of a 2007 report we submitted to Congress, entitled "Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program" (November 21, 2007). This report is available on the CMS Web site at: *http://www.cms.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf*. The report takes into account input from both stakeholders and other interested parties.

As described more fully in the Hospital Inpatient VBP Program proposed rule (76 FR 2458 through 2463), we proposed to initially adopt for the FY 2013 Hospital Inpatient VBP Program 18 measures that we have already adopted for the Hospital IQR Program, categorized into two domains. We proposed to group 17 of the proposed measures, which are clinical process of care measures, into a Clinical Process of Care domain, and proposed to place 1 measure, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, into a Patient Experience of Care domain. We also proposed to use a 3-quarter performance period from July 1, 2011 through March 31, 2012 for these proposed measures for purposes of the FY 2013 Hospital Inpatient VBP Program and to determine whether hospitals meet the proposed performance standards for these measures by comparing their performance during the proposed performance period to their performance during a proposed 9-month (3-quarter) baseline period from July 1, 2009 through March 31, 2010.

We proposed to implement a methodology for assessing the total

performance of each hospital based on performance standards, under which we will score each hospital based on achievement and improvement ranges for each applicable measure. In addition, we proposed for FY 2013 to calculate a total performance score for each hospital by combining the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, multiplying each domain score by a proposed weight (clinical process of care: 70 percent, patient experience of care: 30 percent), and adding together the weighted domain scores. We proposed to convert each hospital's total performance score into a value-based incentive payment utilizing a linear exchange function. We refer readers to the Hospital Inpatient VBP Program proposed rule for greater detail on all of these proposals.

3. Proposed FY 2014 Hospital Inpatient VBP Program Measures

a. Background

Section 1886(o)(2)(A) of the Act requires the Secretary to select for the Hospital Inpatient VBP Program measures, other than readmission measures, from the measures specified under section 1886(b)(3)(B)(viii) of the Act for the Hospital IQR Program. Section 1886(o)(2)(B)(i) of the Act requires the Secretary, with respect to value-based incentive payments made for discharges occurring during FY 2013, to ensure that the selected measures cover at least the following specified conditions or topics: Acute Myocardial Infarction (AMI); Heart Failure (HF); Pneumonia (PN); Surgeries, as measured by the Surgical Care Improvement Project (SCIP); Healthcare-Associated Infections (HAIs), as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent HAIs (available at: *http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html)* (or any successor plan); and HCAHPS. Section 1886(o)(2)(B)(ii) of the Act requires the Secretary, with respect to value-based incentive payments made for discharges occurring during FY 2014 or a subsequent year, to ensure that Hospital Inpatient VBP Program measures include efficiency measures, including measures of Medicare spending per beneficiary.

Section 1886(o)(2)(C)(i) of the Act provides that the Secretary may not select a measure with respect to a performance period for a fiscal year unless the measure has been specified under the Hospital IQR Program and included on the *Hospital Compare* Web site for at least one year prior to the beginning of the performance period. Section 1886(o)(2)(C)(ii) of the Act provides that a measure selected under section 1886(o)(2)(A) of the Act shall not apply to a hospital if the hospital does not furnish services appropriate to the measure.

b. Proposed Efficiency Measure—Medicare Spending per Beneficiary Measure—for the FY 2014 Hospital Inpatient VBP Program

(1) Introduction

Section 1886(o)(2)(B)(ii) of the Act requires the Secretary to ensure that, for Hospital Inpatient VBP discharges occurring during FY 2014 or a subsequent year, the measures selected "include efficiency measures, including measures of 'Medicare spending per beneficiary'. * * *" Therefore, for the FY 2014 Hospital Inpatient VBP Program, we are proposing to adopt a Medicare spending per beneficiary measure. This measure also is proposed for inclusion in the Hospital IQR Program in this proposed rule and is described in detail above in section IV.A.3.b.(2)(B)(v). The proposed approach to scoring this measure and including it in the Hospital Inpatient VBP Program is described below.

(2) Scoring the Medicare Spending Per Beneficiary Measure

Section 1886(o)(5)(B)(ii) of the Act requires that the hospital performance score be determined using the higher of its achievement or improvement score for each measure. Therefore, we are proposing to calculate each hospital's achievement score and improvement score on the proposed Medicare spending per beneficiary measure, in order to determine which score will be used to calculate the total performance score for the hospital.

We are proposing this scoring methodology because it is generally similar to the methodology proposed for scoring the Clinical Process of Care and Outcome Measures in the Hospital Inpatient VBP Program proposed rule (76 FR 2465 through 2471).

(A) Scoring Based on Achievement

We are proposing to calculate a Medicare per beneficiary spending ratio of the Medicare spending per beneficiary amount for each hospital to the median Medicare spending per beneficiary amount across all hospitals during the performance period. We are proposing that a hospital would earn between 1 and 10 achievement points on the Medicare spending per beneficiary measure if its individual Medicare spending per beneficiary ratio during the performance period falls at or between the achievement threshold and the achievement benchmark for the measure. We are proposing to set the achievement threshold at the median Medicare spending per beneficiary ratio across all hospitals during the performance period. We are proposing to set the benchmark at the mean of the lowest decile of Medicare spending per beneficiary ratios during the performance period. A hospital whose individual Medicare spending per beneficiary ratio falls below the achievement threshold would score 0 achievement points on the measure, and a hospital whose individual Medicare spending per beneficiary ratio falls at or above the achievement benchmark would score the maximum of 10 achievement points on the measure. A hospital whose individual Medicare spending per beneficiary ratio falls at or above the achievement threshold, but below the benchmark, would score between 1–9 points according to the following formula:

[9 * ((Hospital's performance period score − achievement threshold)/(benchmark − achievement threshold))] + .5

(B) Scoring Based on Improvement

We are proposing that a hospital would earn between 1 and 9 improvement points on the proposed Medicare spending per beneficiary measure if its individual Medicare spending per beneficiary ratio during the performance period falls within the improvement range. We are proposing to set the threshold for improvement at the hospital's own Medicare spending per beneficiary ratio, as calculated during the baseline period. We are proposing a baseline period of May 15, 2010 through February 14, 2011 for the Medicare spending per beneficiary measure and discuss this proposal in section IV.B.3.b.(4) of the preamble of this proposed rule. We are proposing that the improvement benchmark would be equal to the achievement benchmark for the performance period, which is the mean of the lowest decile of Medicare spending per beneficiary ratios across all hospitals. A hospital whose Medicare spending per beneficiary ratio is equal to or lower than its baseline period Medicare spending per beneficiary ratio would score 0 improvement points on the measure. If a hospital's score on the measure during the performance period was greater than its baseline period score but below the benchmark (within the improvement range), the hospital would receive a score of 0–9 according to the following formula:

[10 * ((Hospital performance period score − Hospital baseline period score)/(Benchmark − Hospital baseline period score))] − .5

(C) Example of Scoring the Medicare Spending per Beneficiary Measure

If Hospital A had the following spending per beneficiary amounts during the baseline and performance period:

Baseline = $10,105
Performance = $9,125;

and the median spending per beneficiary amounts across all hospitals for the baseline and performance periods were:

Median Baseline = $11,672
Median Performance = $12,467;

then the Medicare spending per beneficiary ratios for Hospital A in the baseline and performance periods would be:

Baseline Ratio = 0.866
Performance Ratio = 0.732.

With an achievement threshold of 1.0 and an achievement benchmark of 0.712, we would then calculate attainment and improvement points for Hospital A as follows:

Attainment Points = 9 * (1.0 − 0.732)/(1.0 − 0.712) + 0.5 = 8.868
Improvement Points = 10 * (0.866 − 0.732)/(0.866 − 0.712) − 0.5 = 8.185

These points are rounded to yield 9 attainment points and 8 improvement points.

Because section 1886(o)(5)(B)(ii) of the Act, as added by section 3001 of the Affordable Care Act, requires that the hospital performance score will be determined using the higher of attainment or improvement score for each measure, the hospital in this example would receive 9 points on the Medicare spending per beneficiary measure.

(D) Incorporation of Medicare Spending per Beneficiary Measure Score Into the Overall Hospital Total Performance Score

We are proposing to incorporate the Medicare spending per beneficiary measure score into the FY 2014 Hospital Inpatient VBP Program as part of a new domain: The "Efficiency" domain. The Medicare spending per beneficiary measure score would be the Efficiency domain score for purposes of the FY 2014 Hospital Inpatient VBP Program. Consistent with the domain scoring method proposed in the Hospital Inpatient VBP Program proposed rule (76 FR 2454 through 2491), we are proposing to determine the total earned points for the Efficiency domain in general by adding the points earned for each domain measure and dividing by the total possible points, then multiplying that number by 100 percent. However, because we are proposing to adopt only one measure for the Efficiency domain for the FY 2014 Hospital Inpatient VBP Program, the total points earned for the domain would be the points earned on the Medicare spending per beneficiary measure. We are proposing that the total possible points that a hospital could earn for the Efficiency domain for FY 2014 would be 10, which is equal to the total possible points that the hospital could earn for the Medicare spending per beneficiary measure. We are proposing that the Efficiency domain percentage score would be calculated for FY 2014 as follows: Efficiency domain score = Total points earned on the Medicare spending per beneficiary measure divided by 10, then multiplied by 100 percent.

Once the Efficiency domain score has been determined, we are proposing to assign it a weight for use in the calculation of the total performance score. We intend to propose FY 2014 domain weighting, any additional FY 2014 measures, and other FY 2014 proposals for the Hospital Inpatient VBP Program in the CY 2012 Hospital Outpatient Prospective Payment System proposed rule.

4. Proposed Efficiency Domain (Medicare Spending per Beneficiary Measure) Performance Period and Baseline Period

Section 1886(o)(2)(C)(i) of the Act prohibits the Secretary from selecting a measure for the Hospital Inpatient VBP Program with respect to a performance period unless it has been specified under the Hospital IQR Program and included on the *Hospital Compare* Web site for at least 1 year prior to the beginning of such performance period. Section 1886(o)(8) of the Act requires that hospitals be notified of the calculation of their value-based incentive payment no later than 60 days prior to the fiscal year involved. In order to comply with these statutory requirements for the FY 2014 Hospital Inpatient VBP Program, we are proposing to adopt a 9-month period of performance from May 15, 2012 through February 14, 2013 for the proposed Medicare spending per beneficiary measure. If the measure is adopted, this would allow for a 1-year display period on *Hospital Compare,* a 60-day notification period, and would allow the time needed for administrative processes. We note that this would mean that only IPPS discharges occurring from May 15, 2012 through 90 days prior to February 14, 2013 would count as index stays for purposes of creating the Medicare spending per beneficiary episodes. The Medicare spending per beneficiary episode is described in section IV.A.3.b.(2).(B).(v) of this proposed rule.

For the purposes of calculating improvement points on the proposed Medicare spending per beneficiary measure, it is necessary to establish the baseline period to which the performance period score will be compared. For purposes of the FY 2014 Hospital Inpatient VBP Program, we are proposing to adopt a baseline period of May 15, 2010 through 90 days prior to February 14, 2011 for this proposed measure. The proposed baseline period is consistent with the baseline period that has been proposed for the FY 2013 clinical process of care and patient experience of care measures in the Hospital Inpatient VBP Program proposed rule (76 FR 2454 through 2491) because it precedes the performance period by 2 years.

We invite public comment on all of our proposals related to the Efficiency Domain and Medicare spending per beneficiary measure.

5. Proposal to Simultaneously Specify Additional Measures for the Hospital Inpatient VBP Program and Adoption Into the Hospital IQR Program

We are proposing to simultaneously specify additional measures for the Hospital Inpatient VBP Program and adoption into the Hospital IQR Program, as appropriate for usage in both programs. Our rationale is to improve patient safety and quality of care in an expedited manner that is compliant with applicable statutory guidance. We are currently utilizing this approach in this rule by proposing to add the Medicare Spending per Beneficiary measure to both Hospital Inpatient VBP and Hospital IQR Programs. We will provide all associated regulatory impact and policy rationale in future proposals for both programs. We believe that this proposal notifies stakeholders through rulemaking and welcome comments on this proposal.

C. Hospital Readmissions Reduction Program

1. Background

a. Overview

CMS is committed to promoting high quality health care and improving patient health outcomes. Readmission to a hospital may be an adverse event for patients and many times imposes a

financial burden on the health care system. Successful efforts to reduce preventable readmission rates will improve quality of care while simultaneously decreasing costs. Hospitals can work with their communities to lower readmission rates and improve patient care in a number of ways, such as ensuring patients are clinically ready to be discharged, reducing infection risk, reconciling medications, improving communication with community providers responsible for post-discharge patient care, improving care transitions, and ensuring that patients understand their care plans upon discharge.

Many studies have demonstrated the effectiveness of these types of in-hospital and post-discharge interventions in reducing the risk of readmission, confirming that hospitals and their partners have the ability to lower readmission rates.[34] [35] [36] These types of efforts taken during and after a hospitalization have been shown to be effective in reducing readmission rates in geriatric populations generally, [37] [38] as well as for multiple specific conditions. Moreover, such interventions can be cost saving. For example, in the case of heart failure, improved hospital [39] and post-discharge care,[40] [41] including pre-discharge planning,[42] [43] home-based follow-up, and patient education,[44] [45] have been shown to lower heart failure readmission rates, suggesting that heart failure readmission rates might be reduced if proven interventions were more widely adopted. Financial incentives to reduce readmissions will in turn promote improvement in care transitions and care coordination, as these are important means of reducing preventable readmissions.[46]

In its 2007 "Report to Congress: Promoting Better Efficiency in Medicare," [47] MedPAC noted the potential benefit to patients of lowering readmissions and suggested payment strategies that would incentivize hospitals to reduce these rates. MedPAC identified 7 conditions and procedures that accounted for almost 30 percent of potentially preventable readmissions: heart failure; chronic obstructive pulmonary disease; pneumonia; acute myocardial infarction; coronary artery bypass graft surgery; percutaneous transluminal coronary angioplasty; and other vascular procedures. To promote quality of care, CMS developed hospital quality of care measures that compare patient outcomes across different hospitals. These measures, including hospital risk-standardized readmission measures for Acute Myocardial Infarction (AMI), Heart Failure (HF) and Pneumonia (PN), were originally developed for public reporting as a part of the Hospital IQR Program. We adopted the HF readmission measure for the Hospital IQR Program in the FY 2009 IPPS final rule for the FY 2010 payment determination (73 FR 48606) and the AMI and PN readmission measures in the CY 2009 OPPS/ASC final rule with comment period for the FY 2010 payment determination (73 FR 68781). Details about the methodology used for these measures may be found online at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

As described above, readmission rates are important markers of quality of care, particularly of the care of a patient in transition from an acute care setting to a non-acute care setting, and improving readmissions can positively influence patient outcomes and the cost of care. The above hospital risk-standardized readmission measures are endorsed by the National Quality Forum (NQF) and have been publicly reported on *Hospital Compare* Web site since 2009 (*http://www.hospitalcompare.hhs.gov*) to encourage quality improvement and lower readmission rates. As discussed in detail below, we are now proposing that the readmission measures for these three conditions be used for the Hospital Readmission Reduction Program under section 1886(q) of the Act, as added by Section 3025 of the Affordable Care Act.

b. Statutory Basis for the Hospital Readmission Reduction Program

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added a new subsection (q) to section 1886 of the Act. Section 1886(q) of the Act establishes the "Readmission Reduction Program" effective for discharges from an "applicable hospital" beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions.

In this year's IPPS rulemaking, we address: (i) Those aspects of the program that relate to the conditions and readmissions to which the program will apply for the first program year beginning October 1, 2012; (ii) the readmission measures and related methodology used for those measures, as well as the calculation of the readmission rates; and (iii) public reporting of the readmission data. Specific information regarding the payment adjustment required under section 1886(q) of the Act will be proposed in next year's IPPS/LTCH PPS proposed rule. Although we are not proposing specific policies regarding the payment adjustment under the Hospital Readmissions Reduction Program in this proposed rule, we believe that it is still important to set forth the general framework of the Hospital Readmissions Reduction Program, including the payment adjustment provisions, in

[34] Gwadry-Sridhar FH, Flintoft V, Lee DS, Lee H, Guyatt GH: A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. Arch Intern Med. 2004;164(21):2315–2320.

[35] McAlister FA, Lawson FM, Teo KK, Armstrong PW.: A systematic review of randomized trials of disease management programs in heart failure. AmJMed. 2001;110(5):378–384.

[36] Krumholz HM, Amatruda J, Smith GL, *et al.:* Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. J Am Coll Cardiol. 2002;39(1):83–89.

[37] Coleman EA, Parry C, Chalmers S, Min SJ.: The care transitions intervention: results of a randomized controlled trial. Arch Intern Med. 2006;166:1822–8.

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[39] Gwadry-Sridhar FH, Flintoft V, Lee DS, Lee H, Guyatt GH.: A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. Arch Intern Med. 2004;164(21):2315–2320.

[40] Lappe JM, Muhlestein JB, Lappe´ DL, *et al.:* Improvements in 1-year cardiovascular clinical outcomes associated with a hospital-based discharge medication program. Ann Intern Med. 2004;141(6):446–453.

[41] Phillips CO, Wright SM, Kern DE, Singa RM, Shepperd S, Rubin HR.: Comprehensive discharge planning with postdischarge support for older patients with congestive heart failure: a metaanalysis [published correction appears in JAMA. 2004;292(9):1022]. JAMA. 2004;291(11):1358–1367.

[42] Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, Carney RM.: A multi disciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. N Engl J Med. 1995;333(18):1190–1195.

[43] Schneider JK, Hornberger S, Booker J, Davis A, Kralicek R.: A medication discharge planning program: measuring the effect on readmissions. Clin Nurs Res. 1993;2(1):41–53.

[44] Koelling TM, Johnson ML, Cody RJ, Aaronson KD.: Discharge education improves clinical outcomes in patients with chronic heart failure. Circulation. 2005;111(2):179–185.

[45] Krumholz HM, Amatruda J, Smith GL, *et al.:* Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. J Am Coll Cardiol. 2002;39(1):83–89.

[46] Coleman EA.: 2005. Background Paper on Transitional Care Performance Measurement. Appendix I. In: Institute of Medicine, Performance Measurement: Accelerating Improvement. Washington, DC: National Academy Press.

[47] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at *http://www.medpac.gov/documents/Jun07_EntireReport.pdf.* Accessed January 10, 2011.

order for the public to understand how the proposed measures outlined in this rulemaking will affect certain hospital payments beginning in FY 2013.

Section 1886(q)(1) of the Act sets forth the methodology by which payments to "applicable hospitals" will be adjusted to account for excess readmissions. Pursuant to section 1886(q)(1) of the Act, payments for discharges from an "applicable hospital" will be an amount equal to the product of the "base operating DRG payment amount" and the adjustment factor for the hospital for the fiscal year. That is, the "base operating DRG payments" are reduced by an adjustment factor that accounts for excess readmissions. Section 1886(q)(1) of the Act requires the Secretary to make payments for a discharge in an amount equal to the product of "the base operating DRG payment amount" and "the adjustment factor" for the hospital in a given fiscal year. Section 1886(q)(2) of the Act defines the base operating DRG payment amount as "the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o) [the Hospital VBP Program]) for a discharge if this subsection did not apply; reduced by * * * any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d)." Paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection(d) refer to outlier payments, IME payments, DSH payments, and payments for low volume hospitals, respectively.

Furthermore, section 1886(q)(2)(B) of the Act specifies special rules for defining "the payment amount that would otherwise be made under subsection (d)" for certain hospitals. Specifically, section 1886(q)(2)(B) of Act states that "[i]n the case of a Medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal years 2012 and 2013) or a sole community hospital * * * the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5)." We intend to propose regulations to implement the statutory provisions related to the definition of "base operating DRG payment amount" in the FY 2013 IPPS/LTCH PPS proposed rule.

Section 1886(q)(3)(A) of the Act defines the "adjustment factor" for an applicable hospital for a fiscal year as equal to the greater of "(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C)." Section 1886(q)(3)(B) of the Act in turn describes the ratio used to calculate the adjustment factor. It states that the ratio is "equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions * * *; and (ii) the aggregate payments for all discharges. * * *" Section 1886(q)(3)(C) of the Act describes the floor adjustment factor, which is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

Section 1886(q)(4) of the Act sets forth the definitions of "aggregate payments for excess readmissions" and "aggregate payments for all discharges" for an applicable hospital for the applicable period. The term "aggregate payments for excess readmissions" is defined in section 1886(q)(4)(A) of the Act as "the sum, for applicable conditions * * * of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the "Excess Readmission Ratio* * * for such hospital for such applicable period minus 1." The "Excess Readmission Ratio" is a hospital-specific ratio hospital-specific ratio based on each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the Excess Readmission Ratio as the ratio of "risk-adjusted readmissions based on actual readmissions" for an applicable hospital for each applicable condition, to the "risk-adjusted expected readmissions" for the applicable hospital for the applicable condition.

Section 1886(q)(5) of the Act provides definitions of "applicable condition," "expansion of applicable conditions," "applicable hospital," "applicable period," and "readmission." The term "applicable condition," which we address in detail in this proposed rule, is defined as a "condition or procedure selected by the Secretary among conditions and procedures for which: (i) readmissions * * * represent conditions or procedures that are high volume or high expenditures * * * and (ii) measures of such readmissions * * * have been endorsed by the entity with a contract under section 1890(a) * * * and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital)." The term "expansion of the applicable condition" refers to the Secretary's authority, beginning with fiscal year 2015, "to the extent practicable, [to] expand the applicable conditions beyond the 3 conditions for which measures have been endorsed * * * to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary."

Section 1886(q)(5)(C) of the Act defines "applicable hospital," that is, a hospital subject to the readmission reduction program, as a "subsection (d) hospital or a hospital that is paid under section 1814(b)(3) [of the Act], as the case may be." The term "applicable period," as defined by section 1886(q)(5)(D) of the Act, "means, with respect to a fiscal year, such period as the Secretary shall specify." As explained in this proposed rule, the "applicable period" is the period from which data are collected in order to calculate various ratios and adjustments under the Hospital Readmissions Reduction Program.

Section 1886(q)(6) of the Act sets forth the reporting requirements for hospital-specific readmission rates. Section 1886(q)(7) of the Act limits administrative and judicial review of certain determinations made pursuant to section 1886(q) of the Act. Finally, section 1886(q)(8) of the Act requires the Secretary to collect data on readmission rates for all hospital inpatients for "specified hospitals" in order to calculate the hospital-specific readmission rates for all hospital inpatients and to publicly report these readmission rates.

2. Implementation of the Hospital Readmissions Reduction Program

a. Overview

We intend to implement the requirements of the Hospital Readmissions Reduction Program in the FY 2012, FY 2013, and future IPPS/LTCH PPS rulemaking cycles.

b. Proposed Provisions in the FY 2012 IPPS/LTCH PPS Rulemaking

As explained above, the adjustment factor set forth in section 1886(q) of the Act does not apply to discharges until FY 2013. Therefore, we are able to implement the Hospital Readmission Reduction Program over two years. We are first addressing issues such as the selection of readmission measures and the calculation of the excess readmission ratio, which will then be used, in part, to calculate the readmission payment adjustment factor. Specifically, in the FY 2012 IPPS

rulemaking, we are addressing portions of section 1886(q) of the Act related to the following provisions:

- Selection of applicable conditions;
- Definition of "readmission;"
- Measures for the applicable conditions chosen for readmission;
- Methodology for calculating the Excess Readmission Ratio;
- Public reporting of the readmission data; and
- Definition of "applicable period."

With respect to the topics of "measures for readmission" for the applicable conditions, and "methodology for calculating the Excess Readmission Ratio," we will specifically address the following:

- Index hospitalizations;
- Risk Adjustment;
- Risk Standardized Readmission Rate;
- Data sources; and
- Exclusion of Certain Readmissions.

c. Proposed Provisions To Be Included in the FY 2013 IPPS/LTCH PPS Proposed Rule

In the FY 2013 IPPS rulemaking, we will address the provisions in section 1886(q) of the Act that are related to the payment adjustment, as well as the rest of the provisions in section 1886(q) of the Act that are not addressed in the FY 2012 IPPS/LTCH PPS rulemaking. Specifically, in the FY 2013 IPPS/LTCH proposed rule, we plan to address section 1886(q) of the Act related to the following provisions:

- Base operating DRG payment amount, including policies for SCHs and MDHs;
- Adjustment factor (both the ratio and floor adjustment factor);
- Aggregate payments for excess readmissions;
- Applicable hospital; and

We believe it is appropriate to first address the readmission measures and the calculation of the excess readmission ratio that will then be used, in part, to calculate the readmission payment adjustment factor and the application of the readmission payment adjustment factor to inpatient hospital payments. We believe the 2-year rulemaking schedule provides adequate time and opportunities for careful consideration of the various aspects of this program by both CMS and stakeholders prior to implementation of the Hospital Readmission Reduction Program in FY 2013.

d. Proposed Expansion of the Applicable Conditions To Be Included in the Future Rulemaking

Pursuant to section 1886(q)(5)(B) of the Act, the Secretary "shall, to the extent practicable," expand the list of applicable conditions beyond the 3 conditions for which measures have been endorsed and add 4 conditions that have been identified by MedPAC for the Hospital Readmission Reduction Program. We plan to implement this section of the Act in later rulemaking.

3. Proposed Provisions for the Hospital Readmission Reduction Program

a. Proposed Applicable Conditions for the FY 2013 Hospital Readmission Reduction Program

Section 1886(q) of the Act sets forth payment adjustments for applicable hospitals to account for excess readmissions, for applicable conditions, that are high volume or high expenditure, in the hospital. These payment adjustments are determined based on the occurrence of readmissions for "applicable conditions." When selecting "applicable conditions," the Secretary must select among conditions and procedures for which (1) readmissions are "high volume or high expenditure; and (2) "measures of such readmissions" have been endorsed by the entity with a contract under section 1890(a) of the Act (currently NQF) and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge. Consistent with these requirements, we are proposing to include AMI, HF and PN as "applicable conditions" for the Hospital Readmissions Reduction Program in FY 2013 and subsequent fiscal years. As set forth below, we believe these conditions meet the criteria for "applicable conditions" under section 1886(q)(5)(A) of the Act. We also note that in the 2007 Report to Congress that we referred to earlier in the overview section, MedPAC listed three conditions: AMI, HF, and PN, as priorities for hospital-specific public reporting of readmission rates.[48]

With regards to the first criterion, that readmissions of "applicable conditions" be "high volume or high expenditure," MedPAC identified AMI, HF, PN as being among the seven conditions and procedures associated with approximately 30 percent of potentially preventable readmissions,[49] based on an 3M analysis conducted for MedPAC of 2005 MedPAR (Medicare FFS hospital claims). Of these seven conditions and procedures, HF and PN were the highest in terms of volume and expenditures.

Additionally, in our analysis of the 235 diagnostic categories for hospitalization based on 2008 Medicare hospital claims data, HF and PN were first and second, respectively, as the most frequent diagnostic category for both total admissions and total readmissions. AMI was ninth among the 235 conditions in terms of frequency of admission and 8th in frequency of readmission. We therefore believe that AMI, HF and PN consitute high volume and high expenditure conditions particularly as relates to hospital admission and readmission.

With regards to the second criterion, we believe that measures of readmissions for these applicable conditions also meet the statutory requirements. Section 1886(q)(5)(A)(i) of the Act requires that each "applicable condition" have "measures of readmissions" that "(I) have been endorsed by the entity with a contract under section 1890(a); and (II) such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge." As discussed in section IV.C.3.c. below, we believe that our proposal to select AMI, HF, and PN as "applicable conditions" is consistent with this statutory requirement. The NQF (the entity with a contract under section 1890(a) of the Act) has endorsed "measures of readmissions" for each of these three conditions, and those NQF-endorsed measures "have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital)."

We believe AMI, HF, and PN meet both prongs of the definition of "applicable condition." Therefore, we are proposing to include AMI, HF, and PN as "applicable conditions" for the Hospital Readmissions Reduction Program for FY 2013 and subsequent fiscal years. We invite public comment on this proposal.

b. Proposed Definition of "Readmission"

Section 1886(q)(5)(E) of the Act defines "readmission" as, "in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge." The definition further states that "[i]nsofar as the discharge relates to an applicable condition for which there is an endorsed measure * * * such time period (such as 30 days) shall be

[48] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at *http://www.medpac.gov/documents/Jun07_EntireReport.pdf*. Accessed January 10, 2011.

[49] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at *http://www.medpac.gov/documents/Jun07_EntireReport.pdf*. Accessed January 10, 2011.

consistent with the time period specified for such measure."

The three NQF-endorsed readmission measures define a readmission as occurring when a patient is discharged from the applicable hospital to a non-acute setting (for example, home health, skilled nursing, rehabilitation or home) and then is admitted to the same or another acute care hospital within a specified time period from the time of discharge from the index hospitalization. The time period specified for these measures is 30 days. Because the measures as endorsed by NQF are calculated based on readmissions occurring within 30 days, we are proposing 30 days as the time period specified from the date of discharge for the purpose of defining readmission for the purpose of the Hospital Readmissions Reduction Program. This is in compliance with the statutory requirement that the time period specified by the Secretary from the date of discharge for the purpose of defining readmission be consistent with the time period specified for the endorsed measures. We invite public comment on our proposal to adopt, without revision, a proposed definition of readmission with a time period of 30 days from the date of discharge from the index hospital as set forth in the existing NQF-endorsed measures.

c. Proposed Readmission Measures and Related Methodology

(1) Proposed Readmission Measures for Applicable Conditions

As explained above, section 1886(q)(5)(A)(ii) of the Act requires that each "applicable condition" selected by the Secretary have "measures of readmissions" that "have been endorsed by the entity with a contract under section 1890(a)" and that "such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge." We are proposing to adopt three NQF-endorsed, hospital risk-standardized readmission measures for AMI, HF, and PN which are currently included in the Hospital IQR Program. These existing measures are:

- Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure (NQF# 0505);
- Heart Failure 30-day Risk Standardized Readmission Measure (NQF#0330); and
- Pneumonia 30-day Risk Standardized Readmission Measure (NQF#0506).

CMS adopted these measures for the Hospital IQR Program in the FY 2009 IPPS/LTCH final rule for FY 2010 payment determination (73 FR 48606) and the CY 2009 OPPS/ASC final rule with comment period (73 FR 68781). The NQF (the entity with a contract under section 1890(a) of the Act) has endorsed each of these "measures of readmissions" and, as explained in more detail below, those NQF-endorsed measures "have exclusions for readmissions that are unrelated to the prior discharge." Therefore, we believe these measures meet the statutory requirements for selection for the Hospital Readmissions Reduction Program, and we are proposing them, without modification, as measures for the program.

(2) NQF Endorsement of Measures of Readmissions

We note that these measures and their underlying methodologies were endorsed by NQF. We are proposing to adopt, for purposes of the Hospital Readmissions Reduction Program, the measures and related methodologies as they are currently endorsed by NQF. This includes the currently endorsed 30-day time window, risk-adjustment methodology, and exclusions for certain readmissions that comprise the measures. We believe that this proposal to adopt, without modification, these measures of readmission is consistent with the statutory language, which requires the measures of readmissions to be "endorsed by the entity with a contract under section 1890(a)." If we were to modify the endorsed measures, we are concerned that they would no longer be considered "endorsed." If the NQF were to later endorse a revised measure for one of these conditions, we would then propose through notice and comment rulemaking that the revised measure be used prospectively for purposes of the Hospital Readmissions Reduction Program.

We welcome public comment on this proposal to use, for each of the proposed applicable conditions, existing measures as endorsed by the NQF.

(3) Endorsed Measures With Exclusions for Unrelated Readmissions

Section 1886(q)(5)(A)(i)(ii)(II) of the Act requires that each of the readmission measures also has "exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital)." The three NQF-endorsed readmission measures that we are proposing for inclusion in the Hospital Readmissions Reduction Program have exclusions that meet this statutory requirement. Under each measure, certain unrelated readmissions are not taken into account when determining the number of readmissions under the measures.

The AMI 30-day risk standardized readmission measure, as endorsed by the NQF and as proposed in this rule, has exclusions for certain unrelated readmissions. Because admissions for Percutaneous Transluminal Coronary Angioplasty (PTCA) or Coronary Artery Bypass Graft (CABG) may be staged or are typically scheduled readmissions for patients initially admitted for AMI, the AMI 30-day risk standardized readmission measure does not count as readmissions those admissions after discharge that include PTCA or CABG procedures, unless the principal discharge diagnosis for the readmission is one of the following diagnoses that are not consistent with a scheduled readmission: heart failure, acute myocardial infarction, unstable angina, arrhythmia, and cardiac arrest (that is, readmissions with these diagnoses and a PTCA or CABG procedure are counted as readmissions). We adopted this approach when first developing this measure after consultation with clinical experts, including cardiologists, and review of relevant readmissions data.

During the development of the readmission measures for both HF and PN, we similarly asked clinical experts to identify planned readmissions for these conditions, that is, those which would not count as a readmission, after an admission for HF or PN. Specifically, the clinical experts were asked whether there were common follow-up causes of readmissions for a scheduled procedure that represented a continuation of care after either a HF or PN admission, respectively. No such related, planned procedures were identified as occurring commonly after the index admissions for HF or PN at the time of the development of the IQR measures. Therefore, no similar exclusions exist for the HF and PN measures of readmissions as they are currently endorsed.

Under the three NQF-endorsed risk-standardized readmission measures that we are proposing in this proposed rule, transfers to other acute care facilities are excluded from each of the readmission measures. The NQF-endorsed proposed measures consider these multiple contiguous hospitalizations to be a single acute episode of care. The measures attribute the readmission for transferred patients to the hospital that ultimately discharges the patient to a non-acute care setting (for example, to home or a skilled nursing facility). Thus, in the case of a patient who is transferred between two or more hospitals, if the patient is readmitted in the 30 days following the final

hospitalization, the measures attribute such a readmission to the hospital that discharged the patient to a non-acute care setting. We believe that the exclusion of transfers to other applicable hospitals under the measures is sufficient to meet the requirement set forth in section 1886(q)(5)(A)(ii)(II) of the Act that certain "unrelated" readmissions be excluded from the measures selected for use in the program. We invite public comment on our proposal to adopt, without revision or modification, the exclusions for unrelated admissions set forth in the existing NQF-endorsed measures.

(4) Methodology of Proposed Readmission Measures

In the following section, we describe the major components of the measure methodology of the three NQF-endorsed risk-standardized readmission measures for AMI, HF and PN proposed for the implementation of the Hospital Readmissions Reduction Program. Additional details about each of these measures may be found online at *http://www.QualityNet.org* > Hospital-Inpatient > Readmission Measures > methodologies. This Web page is located at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

Briefly, as is described in more detail in the sections below, the measures are risk-standardized rates of readmission. For each hospital qualifying index hospitalizations are identified based on the principal discharge diagnosis of the patient and the inclusion/exclusion criteria (section IV.C.3.c.(4)(A), Index hospitalization). Each hospitalization is evaluated for whether the patient had a readmission to an acute care setting in the 30-days following discharge (section IV.C.3.c.(4)(B), Readmission). Patient-risk factors, including age, and chronic medical conditions are also identified from inpatient and outpatient claims for the 12-months prior to the hospitalization for risk-adjustment (section IV.C.3.c.(4)(D), Risk-Adjustment). The readmissions, sample size for each hospital, and patient risk-factors are then used to calculate a risk-standardized readmission ratio for each hospital. For the purposes of publicly-reporting the measures, this risk-standardized readmission ratio is then multiplied by the national crude rate of readmission for the given condition to produce a risk-standardized readmission rate (RSRR) (section IV.C.3.c.(5)(B)).

As stated above, we invite public comment on our selection of the three readmission measures, as endorsed by the NQF, and as described in more detail below.

(A) Index Hospitalization

An index hospitalization for each of the readmission measures is the hospitalization from which we evaluate the 30 days after discharge for possible readmissions. The measures, as endorsed by the NQF, evaluate eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital (as defined by section 1886(q)(5)(C) of the Act) having a principal discharge diagnosis for the measured condition in an applicable period. The NQF endorsed measures, as specified, exclude patients under 65 years of age.

The discharge diagnoses for each applicable condition are based on a list of specific ICD–9–CM codes for that condition. These codes are listed in the *2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30-Day Risk-Standardized Readmission Measures.* They also are posted on the QualityNet Web site: *http://www.QualityNet.org* > Hospital-Inpatient > Readmission Measures > methodologies. See *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

The current NQF-endorsed CMS 30-day risk standardized readmission measures exclude the following admissions from the group of index hospitalizations:

- Hospitalizations for patients with an in-hospital death (because they are not eligible for readmission);
- Hospitalizations for patients without at least 30 days post-discharge enrollment in Medicare FFS (because the 30-day readmission outcome cannot be assessed in this group);
- Hospitalizations for patients discharged against medical advice (because providers did not have the opportunity to deliver full care and prepare the patient for discharge).

(B) Readmission

As explained above, the initial hospitalization assessed for a readmission is called the index hospitalization. The proposed measures, as endorsed by the NQF, define readmission as a second admission to another acute care hospital within 30-days of the index hospitalization. Under the proposed measure, as endorsed by the NQF, a patient who is readmitted twice within 30 days simply is counted as having been readmitted; this patient's readmissions are not counted differently than a patient with a single readmission within 30 days of discharge.

With the exception of the exclusions discussed previously (transfers and planned readmissions, as discussed in the Exclusions for Unrelated Readmissions section above), the proposed measures, as currently endorsed by the NQF, include readmissions for all causes, without regard to the principal diagnosis of the readmission. There are several reasons for this approach. First, from the patient's perspective, readmission from any cause is an adverse event. We want the measures to be patient-centered measures. Second, although we would expect few hospitals to use gaming strategies, we strive to make sure that measures do not create incentives for them to do so. Limiting the readmissions to particular diagnoses creates an opportunity for hospitals to potentially avoid having readmissions counted by changing coding practices. Further, do so could create a perverse incentive whereby hospitals begin to avoid patients with conditions that are part of the readmissions measures. Third, there are not clinically and technically sound and accepted strategies for accurately identifying readmission that are unrelated to hospital quality based on the documented cause of readmission. For example, a patient with HF who develops an HAI may ultimately be readmitted for sepsis. It would be inappropriate to consider the readmission as unrelated to the care the patient received for HF. Finally, we believe it is important that hospitals strive to reduce readmissions from all causes, not just those that are readmissions measures; while the measures do not presume that each readmission is preventable, interventions have generally shown reductions in all types of readmissions. The NQF measures are intended to provide incentives for hospitals to reduce readmissions and not to achieve zero readmissions.

(C) Time Window

The three proposed measures, as endorsed by the NQF, count readmissions within a 30-day period from the date of the initial discharge from the index hospitalization. This is the standard time period to be considered a readmission. The timeframe of 30 days is a clinically meaningful period for hospitals, in collaboration with their medical communities, to reduce readmission risk. This time period for assessing readmission is an accepted standard in research and measurement. We believe

that during this 30-day time period, hospital and community partners can take steps to reduce risk by ensuring patients are clinically ready to be discharged, improving communication across providers, reducing risks of infections, and educating patients on symptoms to monitor whom to contact with questions and where and when to seek follow-up care can influence readmission rates.

(D) Risk Adjustment

Section 1886(q)(4)(C)(i)(I) of the Act requires that the number of readmissions used in the Excess Readmission Ratio be risk adjusted. This language requires us, when comparing hospitals' readmission rates, to account for differences in the severity of illness of the patients that hospitals treat. Risk adjustment essentially "levels the playing field" for comparing hospital performance by taking into account that some hospitals' patients are sicker than others on admission and therefore have a higher risk of readmission.

The methodology for calculating the RSRRs under the NQF-endorsed measures that we are proposing adjust for key factors that are clinically relevant and have strong relationships with the outcome (for example, patient demographic factors, patient co-existing medical conditions, and indicators of patient frailty). Under the current NQF-endorsed methodology, these covariates are obtained from Medicare claims extending 12 months prior to, and including, the index admission. This risk-adjustment approach adjusts for differences in the clinical status of the patient at the time of the index admission as well as for demographic variables.

A complete list of the variables used for risk adjustment and the clinical and statistical process for selecting the variables for each NQF-endorsed measure, as proposed, is available in the publicly-available technical documentation of the existing measures for AMI, HF, and pneumonia. The risk adjustment variables for each condition are presented in the 2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30–Day Risk-Standardized Readmissions Measures that are posted on *http://www.QualityNet.org* > Hospital-Inpatient > Readmission Measures > Resources. The variables used are Condition Categories that group ICD–9–CM codes into clinically coherent variables. The 2010 Condition Category-ICD–9–CM Crosswalk provides a map to the specific ICD–9–CM codes in each variable and is also posted on *http://www.QualityNet.org* > Hospital-Inpatient > Readmission Measures > Measure Calculation Methodology or readers may use the following Web site address: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841*

(E) Applicable Period

Section 1886 (q)(5)(D) of the Act authorizes the Secretary to specify the "applicable period" with respect to a fiscal year. Currently, for Hospital IQR Program public reporting purposes, we use three years of data (three 12-month increments) to calculate the three proposed readmission measures. This provides substantially more data than a one or two year time frame and increases the precision of the measure in distinguishing performance among hospitals. This is advantageous in the display of the three proposed readmission measures on *Hospital Compare* where we categorize hospital performance into one of three discrete categories: "Better than the US national rate," "No different than the US national rate," and "Worse than the US national rate."

For the FY 2013 Hospital Readmissions Reduction Program, we are proposing to use 3 years of data for discharges from July 1, 2008 through June 30, 2011 as the applicable period upon which to calculate excess readmission ratios for each of the three proposed measures. Based on our experience with the IQR program, we believe that this timeframe increases the precision of the measures in distinguishing performance among hospitals. However, for purposes of the Hospital Readmissions Reduction Program, we will not be categorizing hospital performance in three categories; rather, we will be using the measures to calculate excess readmission ratios for the three conditions. We are currently conducting analyses to determine an appropriate data period (for example, 1 year, 2 years, 3 years) that will yield reliable excess readmission ratios for the three proposed measures. We intend to consider both the positive and negative consequences of using longer or shorter data periods for this program. Should our analysis or public comment indicate that a shorter data period yields excess readmission ratios with acceptable reliability, we may consider finalizing a shorter time period.

We invite public comment and suggestions on the topic of an appropriate length for the applicable period to consider using for the three proposed readmission measures for the FY 2013 payment determination.

(F) Data Sources

As discussed above, the adjustment under section 1886(q) of the Act is made to the "base operating DRG payment amount," and components of the ratio used to determine a hospital's adjustment factor also use that payment amount. Payments under section 1886 of the Act, including the "base operating DRG payment amount, are made for services furnished to Medicare's fee-for-service population under part A. Therefore, for purposes of implementing the Hospital Readmissions Program under section 1886(q) of the Act, we are proposing to use Medicare claims data for the Medicare FFS population only. This is the same universe of claims used for calculating the endorsed measures for the purposes of the IQR program.

The administrative data sources for the risk adjustment analyses are Medicare administrative claims datasets that contain FFS inpatient and outpatient (Medicare Parts A and B) claims information in the prior 12 months and subsequent one month for patients admitted in each of these years. We are proposing to use claims from the index hospitalization included the measure and from the prior 12 months from all of these data sources to gather risk factors. If the patient does not have any claims in the 12 months prior to the index hospitalization admission, only comorbidities from the included admission are used.

We welcome public comment on this proposal.

(G) Minimum Number of Discharges for Applicable Conditions

Section 1886 (q)(4)(C)(II)(ii) of the Act authorizes the Secretary to exclude readmissions for an applicable condition for which there are "fewer than a minimum number (as determined by the Secretary)." Currently, for public reporting purposes under the IQR program, only hospitals with at least 25 discharges for each of the three proposed applicable conditions are included in the display of the three proposed readmission measures on *Hospital Compare.* We chose this number of discharges for the IQR based on our findings that using fewer cases did not provide sufficiently reliable information on hospital performance. In general the larger the number of cases, the more reliable is the information. We are currently conducting additional analyses to determine further evaluate the appropriate minimum number of discharges needed to yield reliable excess readmission ratios for the three

proposed measures. However, based on our experience with the IQR program, we are proposing to use the current threshold of 25 discharges for each of the three measures for the Hospital Readmissions Reduction Program. However, should our analysis or public comment indicate that a different minimum number of discharges would be more appropriate for this program, we would consider finalizing a different number.

We invite public comment and suggestions on the topic of appropriate minimum number of discharges to consider for the three proposed readmission measures.

(H) Reporting Hospital-Specific Readmission Rates

Section 1886(q)(6)(A) of the Act requires the Secretary to "make information available to the public regarding readmission rates of each subsection (d) hospital under the readmission reduction program." Section 1886(q)(6)(B) of the Act requires the Secretary to "ensure that a subsection (d) hospital has the opportunity to review and submit corrections for, the information to be made public with respect to the hospital * * * prior to such information being made public." Section 1886(q)(6)(C) of the Act requires the Secretary to post the hospital-specific readmission information on the *Hospital Compare* Web site in an easily understandable format.

We currently report information on the three readmission rates we are proposing in this proposed rule on the *Hospital Compare* Web site for each subsection (d) hospital. We provide hospitals with an opportunity to preview their readmission rates for 30-days prior to posting on the Web site. We propose to use a similar process and timeframe for the rates calculated for the Hospital Readmissions Reduction Program. Through this process hospitals will be able to review the information and submit to CMS corrections in advance of the information to be made public. We will carefully review all such correction submissions and determine the appropriateness of any revisions. We will inform the hospital requesting corrections of our findings and we will make any appropriate revisions to the information to be made available to the public regarding the hospital's readmission rates.

We invite public comment on this proposal.

(I) Readmission Rates for All Patients

Section 1886(q)(8)(A) of the Act requires the Secretary to calculate readmission rates for all patients for a "specified hospital" for an applicable condition and "other conditions deemed appropriate by the Secretary for an applicable period." Section 1886(q)(8)(D)(ii) of the Act defines "specified hospital" as: subsection (d) hospitals; hospitals described in clauses (i) through (v) of subsection (d)(1)(B) (psychiatric hospitals, rehabilitation hospitals, children's hospitals, LTCHs, and cancer hospitals); and, "as determined feasible and appropriate by the Secretary, other hospitals." Such information is to be calculated in the same manner as used to calculate readmission rates for hospitals with respect to the postings on the CMS *Hospital Compare* Web site. Section 1886(q)(8)(C) of the Act requires specified hospitals, or a State or an appropriate entity on behalf of the hospitals, to submit to the Secretary, in a form, manner and time specified by the Secretary, data and information determined necessary to calculate the all patient readmission rates. Section 1886(q)(8)(D) of the Act defines "all patients" to mean patients who are treated on an inpatient basis and discharged from a specified hospital. We are not proposing any specific policies to implement section 1886(q)(8) of the Act at this time, but we invite public comment and suggestions for issues related to implementation of these provisions, such as the mechanisms to collect the all-patient data, the collection of patient identifiers to track patient care history across multiple settings to conduct risk adjustment for outcome measures, what entities could submit all patient data on behalf of hospitals, and more generally, the requirement for all patient data submission.

(5) Proposed Excess Readmission Ratio

(A) Statutory Background

Section 1886(q)(4)(C) of the Act requires the Secretary to develop a risk-adjusted "Excess Readmission Ratio." The Excess Readmission Ratio will be used in the calculation of "aggregate payments for excess readmissions" as required under section 1886(q)(4)(A)(iii) of the Act, which, in turn, is used to determine the adjustment factor under section 1886(q)(3). Specifically, section 1886(q)(4)(C)(i) states that the term "'Excess Readmission Ratio' means * * * with respect to an applicable condition for a hospital for an applicable period * * * the ratio of * * * risk adjusted readmissions based on actual readmissions * * * to * * * the risk adjusted expected readmissions." The statute also requires that the numerator and denominator of the ratio, that is, "risk adjusted readmissions based on actual readmissions" and the "risk adjusted expected readmissions," be determined "consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I)."

(B) Proposed Excess Readmission Ratio Methodology

We are proposing to use the risk-standardized ratio calculated for the NQF-endorsed measures for AMI, HF, and PN as the "excess readmission ratio." This risk-standardized ratio (excess readmission ratio), as required by statute, is a ratio of "risk adjusted readmission based on actual" to "risk adjusted expected readmissions." Moreover, use of this ratio meets the statutory requirement that the numerator and denominator of the ratio be determined in a manner that is "consistent with" an NQF-endorsed readmission measure methodology.

The proposed ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (that is, patients with the same risk factors for readmission such as age and comorbidities), the ratio will be less than one. If a hospital performs worse than average, the ratio will be greater than one. Hospitals with a ratio greater than one have excess readmissions relative to average quality hospitals with similar types of patients

As part of the Hospital IQR Program, the risk-standardized ratio to the measure result is reported on *Hospital Compare* Web site. The risk-standardized ratio is the unique result produced by the measures for each hospital for each condition to assess relative hospital performance. Hospitals may not be familiar with this ratio, because the measure result reported on Hospital Compare for each hospital and each condition is this ratio multiplied by a constant (the national raw rate of readmission for the condition), and it is currently presented as the risk-standardized readmission rate (RSRR). Multiplying by a constant transforms the ratio into a rate (the risk-standardized readmission rate) that is better understood by consumers. Thus *Hospital Compare* results for CMS readmission measures are computed as follows:

[Hospital risk-standardized ratio] X [national raw readmission rate] (i) Numerator and Denominator of the Risk-Standardized Ratio (Excess Readmission Ratio)

The NQF-endorsed measures, which we are proposing for the Hospital Readmissions Reduction Program, calculate this risk-standardized ratio (excess readmission ratio) using hierarchical logistic modeling, which is a widely accepted statistical method that evaluates relative hospital performance based on outcomes such as readmission. The method adjusts for variation across hospitals in how sick their patients are when admitted to the hospital (and therefore variation in hospitals' patients' readmission risk) as well as the variation in the number of patients that a hospital treats to reveal difference in quality. The detailed methodology for these measures is publicly-available and the calculation SAS packs are made available upon request. This is the calculation software that permits the measures to be calculated. We describe the key details of the methodology here.

In order to model the extent to which hospitals affect patients' risk of readmission, this statistical model first analyzes data on all the patients discharged from all hospitals for a given condition that indicate for each patient what comorbidities were present when the patient was admitted and whether or not the patient was readmitted and calculates:

- How much variation in hospital readmission rates overall is accounted for by variation across hospitals in patients' individual risk factors (such as age and other medical conditions); a risk weight (beta-coefficient) is calculated for each patient risk factor at all hospitals. The specific approach and variables used in the risk adjustment are discussed below.
- How much variation in readmission rates is accounted for by hospitals' contribution to readmission risk, after adjusting for differences in readmission due to differences in patients' risk factors. The model estimates the amount by which a specific hospital increases or decreases patients' risk of readmission relative to an average hospital based on the hospitals actual readmission relative to hospitals with similar patients. The estimated amount each hospital contributes (or subtracts) from its patients readmission risk compared to hospitals with similar patients is called the "hospital-specific readmission effect." It is used only in the numerator to estimate the adjusted actual readmissions. The hospital-specific effect will be negative for a better than average hospital, positive for a worse than average hospital, and close to zero for an average hospital. If there are no quality differences resulting in excess readmissions among hospitals (if all hospitals had the same readmission rates relative to hospitals with similar patients), the hospital-specific effects for all hospitals will be zero and the ratio for all hospitals will be one.

(ii) Numerator Calculation—Adjusted Actual Readmissions

For each hospital, the numerator of the ratio used in the NQF-endorsed methodology (actual adjusted readmissions) is calculated by estimating the probability of readmission for each patient at that hospital and summing up over all the hospital's patients to get the actual adjusted number of readmissions for that hospital. This estimated probability of readmission for each patient is calculated using:

- The hospital-specific effect (increase, decrease, or no change in probability of readmission relative to the probability of readmission at an average hospital);
- The intercept term for the model (the same for all hospitals and for both numerator and denominator equations);
- The increase or decrease in the probability of readmission contributed by each of the patients' risk factors (risk adjustment coefficients multiplied by the patient's risk factors, X)

Mathematically, the numerator equation can be expressed as:

Numerator: Adjusted Actual Readmissions

Step 1:

Calculate each patient's predicted probability of readmission = $\frac{1}{1 + e^{-Za}}$

Z_a = hospital-specific effect + Xβ

intercept + risk-adjustment coefficients

Step 2:

To get the numerator result, add all patients' predicted probabilities of readmission

(iii) Denominator Calculation—Expected Readmissions (at an Average Quality Hospital Treating the Same Patients)

The denominator of the risk-standardized ratio (excess readmission ratio) under this NQF-endorsed methodology sums the probability of readmission for each patient at an average hospital. This probability is calculated using:

- The intercept term for the model (the same for all hospitals and for both numerator and denominator equations); and
- The increase or decrease in the probability of readmission contributed by each of the patients' risk factors (risk adjustment coefficients multiplied by the patient's risk factors, X).

This can be expressed mathematically as:

Denominator: Expected Readmissions

Step 1:

Calculate each patient's expected probability of readmission = $\frac{1}{1 + e^{-Ze}}$

$Z_e = X\beta$

intercept + risk-adjustment coefficients

Step 2:

To get the denominator result, add all patients' expected probabilities of readmission

Thus, the ratio compares the total adjusted actual readmissions at the hospital to the number that would be expected if the hospital's patients were treated at an average hospital with similar patients. Hospitals with more adjusted actual readmissions than expected readmissions will have a risk-standardized ratio (excess readmission ratio) greater than one.

Because the ratio is risk-adjusted, a hospital may have high crude readmission rates (number of 30-day readmissions among patients with the applicable condition divided by number of admissions for patients with the applicable condition) yet have a risk-standardized ratio (excess readmission ratio) less than one. For example, if a hospital with a higher than average raw readmission rate cares for very sick patients, the ratio may show that the adjusted actual number of readmissions (the numerator), which accounts for the case-mix, is actually lower than what would be expected for an average hospital caring for these patients (denominator) and therefore the Excess Readmission Ratio, as proposed, will be less than one, demonstrating that this hospital performs better than average, despite having a high crude readmission rate, and does not have excess readmissions. Similarly, if a hospital has a seemingly low unadjusted readmission rate but cares for a very low risk population of patients, it may be found to have an adjusted actual number of readmissions that is higher than the expected number of readmissions, and therefore a ratio greater than one.

In summary, we are proposing to use the risk-standardized readmission ratio of the NQF-endorsed readmission measures as the Excess Readmission Ratio. The ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (that is, patients with the same risk factors for readmission such as age and comorbidities), the ratio will be less than 1.0. If a hospital performs worse than average, the ratio will be greater than 1.0.

We welcome public comment on our proposal to use this methodology for calculating the "risk adjusted readmissions based on actual readmissions" as well as the "risk adjusted expected readmissions" used to determine the Excess Readmission Ratio, as set forth in section 1886(q)(5)(C) of the Act.

D. Rural Referral Centers (RRCs) (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as an RRC. For discharges that occurred before October 1, 1994, RRCs received the benefit of payment based on the other urban standardized amount rather than the rural standardized amount (as discussed in the FY 1993 IPPS final rule (59 FR 45404 through 45409)). Although the other urban and rural standardized amounts are the same for discharges occurring on or after October 1, 1994, RRCs continue to receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs are also not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area where the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, "[a]ny hospital classified as an RRC by the Secretary * * * for fiscal year 1991 shall be classified as such an RRC for fiscal year 1998 and each subsequent year." In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), CMS reinstated RRC status for all hospitals that lost the status due to triennial review or MGCRB reclassification. However, CMS did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of "urban" and "rural" specified in Subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the

hospital meets two mandatory prerequisites (a minimum CMI and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (c)(5) and the September 30, 1988 **Federal Register** (53 FR 38513).) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.)

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The proposed national median CMI value for FY 2012 includes data from all urban hospitals nationwide, and the proposed regional values for FY 2012 are the median CMI values of urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These proposed values are based on discharges occurring during FY 2010 (October 1, 2009 through September 30, 2010), and include bills posted to CMS' records through December 2010.

We are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2011, they must have a CMI value for FY 2010 that is at least—

- 1.5292; or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region are set forth in the following table:

Region	Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.3247
2. Middle Atlantic (PA, NJ, NY)	1.3723
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.4579
4. East North Central (IL, IN, MI, OH, WI)	1.4624
5. East South Central (AL, KY, MS, TN)	1.4001
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.4419
7. West South Central (AR, LA, OK, TX)	1.5689
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.6292
9. Pacific (AK, CA, HI, OR, WA)	1.5151

The preceding numbers will be revised in the FY 2012 IPPS final rule to the extent required to reflect the updated FY 2010 MedPAR file, which will contain data from additional bills received through March 2011.

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its fiscal intermediary or MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. We are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2009 (that is, October 1, 2008 through September 30, 2009), which are the latest cost report data available at the time this proposed rule was developed.

Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2011, must have, as the number of discharges for its cost reporting period that began during FY 2009, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located, as indicated in the following table.

Region	Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,141
2. Middle Atlantic (PA, NJ, NY)	11,919
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	11,504
4. East North Central (IL, IN, MI, OH, WI)	8,395
5. East South Central (AL, KY, MS, TN)	7,337
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	8,102
7. West South Central (AR, LA, OK, TX)	5,847
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	9,608
9. Pacific (AK, CA, HI, OR, WA)	8,900

These numbers will be revised in the FY 2012 final rule based on the latest available cost report data.

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, 5,000 discharges is the minimum criterion for all hospitals under this proposed rule.

We reiterate that, if an osteopathic hospital is to qualify for RRC status for cost reporting periods beginning on or after October 1, 2011, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2009.

E. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act, as added by section 406(a) of Public Law 108–173, provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective beginning FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is "in addition to any payment calculated under this section." Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume add-on payment amount is based on all other per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outliers. For SCHs and MDHs, the low-volume add-on payment amount is based on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment. Sections 3125 and 10314 of the Affordable Care Act amended the definition of a low-volume hospital under section 1886(d)(12)(C) of the Act. Sections 3125 and 10314 of the Affordable Care Act also revised the methodology for calculating the payment adjustment for low-volume hospitals.

Prior to the amendments made by the Affordable Care Act, section 1886(d)(12)(C)(i) of the Act defined a low-volume hospital as "a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year." Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term "discharge" means "an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under Part A." Therefore, the term "discharge" refers to total discharges, not merely Medicare discharges. Furthermore, under section 406(a) of Public Law 108–173, which initially added subparagraph (12) to section 1886(d) of the Act, the provision requires the Secretary to determine an applicable percentage increase for these low-volume hospitals based on the "empirical relationship" between "the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges." The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals. The statute also limits the adjustment to no more than 25 percent.

Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25 percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. In the FY 2006 IPPS final rule (70 FR 47432 through 47434), we stated that a multivariate analyses supported the existing low-volume adjustment implemented in FY 2005. Therefore, the low-volume adjustment of an additional 25 percent would continue to be provided for qualifying hospitals with less than 200 discharges.

2. Temporary Changes for FYs 2011 and 2012

Section 1886(d)(12) of the Act was amended by sections 3125 and 10314 of the Affordable Care Act. The changes made by these sections of the Affordable Care Act are effective only for discharges occurring during FYs 2011 and 2012. Beginning with FY 2013, the preexisting low-volume hospital payment adjustment and qualifying criteria, as implemented in FY 2005, will resume. Specifically, as discussed above, the provisions of the Affordable Care Act revised the definition of a low-volume hospital and also revised the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2011 and 2012.

Sections 3125(3) and 10314(1) of the Affordable Care Act amended the

qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act to make it easier for hospitals to qualify for the low-volume adjustment. Specifically, the revised provision specifies that, for FYs 2011 and 2012, a hospital qualifies as a low-volume hospital if it is "more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Part A during the fiscal year." In addition, section 1886(d)(12)(D) of the Act, as added by section 3125(4) and amended by section 10314 of the Affordable Care Act, provides that the payment adjustment (the applicable percentage increase) is to be determined "using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under Part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year."

Section 3125(3)(A) of the Affordable Care Act revised the distance requirement of "25 road miles" to "15 road miles" for FYs 2011 and 2012 such that a low-volume hospital is required to be only more than 15 road miles, rather than more than 25 road miles, from another subsection (d) hospital for purposes of qualifying for the low-volume payment adjustment in FYs 2011 and 2012. The mileage requirement will revert back to "more than 25 road miles" for fiscal years after FY 2012.

Sections 3125(3)(B) and 10314(1) of the Affordable Care Act revised the discharge requirement for FYs 2011 and 2012 to less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A during the fiscal year. Prior to enactment of the Affordable Care Act, under section 1886(d)(12) of the Act, as added by section 406(a) of Public Law 108–173, the discharge requirement to qualify as a low-volume hospital is less than 800 total discharges annually, which includes discharges of both Medicare and non-Medicare patients. This discharge requirement will apply also for fiscal years after FY 2012.

Section 3125(4) of the Affordable Care Act added section 1886(d)(12)(D) to the Act, and section 10314(2) of the Affordable Care Act further modified that section of the Act. Section 1886(d)(12)(D) of the Act, as modified, revises the methodology for calculating the payment adjustment under section 1886(d)(12)(A) of the Act for low-volume hospitals for discharges occurring in FYs 2011 and 2012. For FY 2010 and prior fiscal years, and beginning again in FY 2013, sections 1886(d)(12)(A) and (B) of the Act require the Secretary to determine an applicable percentage increase for low-volume hospitals based on the "empirical relationship" between "the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges." The statute thus requires the Secretary to develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals. The statute also limits the adjustment to no more than 25 percent. Based on analyses we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102) and the FY 2006 IPPS final rule (70 FR 47432 through 47434), a 25 percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. However, section 1886(d)(12)(D) of the Act, as added by the Affordable Care Act, provides that, for discharges occurring in FYs 2011 and 2012, the Secretary shall determine the applicable percentage increase using a continuous linear sliding scale ranging from an additional 25 percent payment adjustment for hospitals with 200 or fewer Medicare discharges to a 0 percent additional payment adjustment for hospitals with more than 1,600 Medicare discharges.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275), we revised our regulations at 42 CFR 412.101 to reflect the changes to the payment adjustment for low-volume hospitals provided for by the provisions of the Affordable Care Act. We also clarified the existing regulations to indicate that a hospital must continue to qualify as a low-volume hospital in order to receive the payment adjustment in that year; that is, it is not based on a one-time qualification. Furthermore, we established a procedure for a hospital to request low-volume hospital status.

Specifically, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 and 50414), we revised our regulations at § 412.101(b)(2)(ii) to provide that, to qualify for the low-volume payment adjustment in FYs 2011 and 2012, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital. We also defined, at § 412.101(a), the term "road miles" to mean "miles" as defined at § 412.92(c)(i). This change in the qualifying criteria from 25 to 15 road miles is applicable only for FYs 2011 and 2012, but the definition of "road miles" continues to apply even after the distance requirement reverts to 25 road miles beginning in FY 2013.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50239 and 50414), we revised our regulations at § 412.101(b)(2)(ii) to provide that, to qualify for the low-volume adjustment in FYs 2011 and 2012, a hospital must have fewer than 1,600 "Medicare discharges" during the fiscal year based on the hospital's Medicare discharges from the most recently available MedPAR data as determined by CMS. We also revised the regulations to specify at § 412.101(a) that the term "Medicare discharges" means a "discharge of inpatients entitled to Medicare Part A, including discharges associated with individuals whose inpatient benefits are exhausted or whose stay was not covered by Medicare and also discharges of individuals enrolled in a MA organization under Medicare Part C."

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240 through 50241), we adopted a continuous linear sliding scale equation to determine the low-volume payment adjustment for FYs 2011 and 2012 for eligible low-volume hospitals with Medicare discharges of *more than 200* and *less than 1,600* (that is, from 201 to 1,599 Medicare discharges). Consistent with the statute, for FYs 2011 and 2012 for eligible low-volume hospitals with *200 or fewer* Medicare discharges, we established a low-volume payment adjustment of 25 percent.

Under the regulations at § 412.101(c)(2), for FYs 2011 and 2012, the low-volume adjustment is determined as follows:

- Low-volume hospitals with *200 or fewer* Medicare discharges will receive a low-volume adjustment of an additional 25 percent for each discharge.
- Low-volume hospitals with Medicare discharges of *more than 200* and *fewer than 1,600* will receive for each discharge a low-volume adjustment of an additional percent calculated using the formula: [(4/14) − (Medicare discharges/5600)]. For additional information on the mathematical interpretation of this formula, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50241).

While we revised the qualifying criteria and the payment adjustment for low-volume hospitals for FYs 2011 and 2012, consistent with the amendments made by the Affordable Care Act, we also noted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240), that we did not modify the process for requesting and obtaining the low-volume hospital payment adjustment. In general, in order to qualify for the low-volume hospital payment adjustment, a hospital must provide to its fiscal intermediary or MAC sufficient evidence to document that it meets the discharge and distance requirements. The fiscal intermediary or MAC will determine, based on the most recent data available, if the hospital qualifies as a low-volume hospital, so that the hospital will know in advance whether or not it will receive a payment adjustment and, if so, the applicable add-on percentage. The fiscal intermediary or MAC and CMS may review available data, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria.

3. Proposed Discharge Data Source to Identify Qualifying Low-Volume Hospitals and Calculate the Payment Adjustment (Percentage Increase) for FY 2012

As described above, for FYs 2005 through 2010 and FY 2013 and subsequent years, since the discharge determination is made based on the hospital's number of total discharges, the hospital's most recently submitted cost report is used to determine if the hospital meets the criteria to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). For FYs 2011 and 2012, the hospital's Medicare discharges from the most recently available MedPAR data, as determined by CMS, are used to determine if the hospital meets the discharge criteria to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(ii)). As also described above, the applicable low-volume percentage increase is determined using a continuous linear sliding scale equation that results in a low-volume adjustment ranging from an additional 25 percent for hospitals with 200 or fewer Medicare discharges to a 0 percent additional payment adjustment for hospitals with 1,600 or more Medicare discharges.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50241), we established that, for FY 2011, the low-volume payment adjustment would be determined using Medicare discharge data for FY 2009 from the March 2010 update of the MedPAR files, as these were the most recent available data. We also stated that we expected to use Medicare claims data from FY 2010 to determine the low-volume payment adjustment for FY 2012, as these would be the most recent available data at that time.

In this proposed rule, we are proposing that, for FY 2012, qualifying low-volume hospitals and their payment adjustment would be determined using Medicare discharge data from the most recent update of the FY 2010 MedPAR file, that is, the December 2010 update, as these data are the most recent data available. Furthermore, we are proposing that if more recent FY 2010 Medicare discharge data are available (such as data from the March 2011 update of the MedPAR files), we would use such data in the final rule. Table 14, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, lists the "subsection (d)" hospitals with fewer than 1,600 Medicare discharges based on the December 2010 update of the FY 2010 MedPAR files and their proposed FY 2012 low-volume payment adjustment. Eligibility for the proposed low-volume payment adjustment for FY 2012 is also dependent upon meeting (if the hospital is qualifying for the low-volume payment adjustment for the first time in FY 2012), or continuing to meet (if the hospital qualified in FY 2011) the mileage criteria specified at § 412.101(b)(2)(ii).

We note that the list of hospitals with fewer than 1,600 Medicare discharges in Table 14 does not reflect whether or not the hospital meets the mileage criterion; that is, the hospital also must be located more than 15 road miles from any other IPPS hospital in order to qualify for a low-volume hospital payment adjustment in FY 2012.

In order to receive a low-volume hospital adjustment payment under § 412.101, a hospital must notify and provide documentation to its fiscal intermediary or MAC that it meets the mileage criterion. The use of a Web-based mapping tool, such as MapQuest, as part of documenting that the hospital meets the mileage criterion for low-volume hospitals, is acceptable. The fiscal intermediary or MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance (in road miles, as defined in the regulations at § 412.101(a)) from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the fiscal intermediary or MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the low-volume mileage criterion. The fiscal intermediary or MAC will refer to the hospital's Medicare discharge data determined by CMS (as proposed for FY 2012 as shown in Table 14, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet), to determine whether or not the hospital meets the discharge criterion, and the amount of the payment adjustment, once it is determined that both the mileage and discharge criteria are met. The Medicare discharge data shown in Table 14, as well as the Medicare discharge data for all "subsection (d)" hospitals with claims in the December 2010 update of the FY 2010 MedPAR files, also will be available on the CMS Web site for hospitals to check their Medicare discharges to help them to decide whether or not to apply for low-volume hospital status.

Similar to the policy we established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 20574 through 20575), we are proposing that, for FY 2012, a hospital make its request for low-volume hospital status in writing to its fiscal intermediary or MAC by September 1, 2011, so that the applicable low-volume percentage add-on would be applied to payments for its discharges beginning on or after October 1, 2011. For FY 2012, we are proposing that a hospital which qualified for the low-volume payment adjustment in FY 2011 may continue to receive a low-volume payment adjustment in FY 2012, without reapplying, if it continues to meet the Medicare discharge criterion, based on the latest available FY 2010 MedPAR data (as proposed above) and the distance criterion. However, the hospital would be required to verify in writing to its fiscal intermediary or MAC that it continues to be more than 15 miles from any other "subsection (d)" hospital no later than September 30, 2011. Further, similar to the policy we established for FY 2011 (Transmittal 2060, Change Request 7134; October 1, 2010), we are proposing that, for requests for low-volume hospital status for FY 2012 received after September 1, 2011, if the hospital meets the criteria to qualify as a low-volume hospital, the fiscal intermediary or MAC would apply the applicable low-volume adjustment in determining payments to the hospital's FY 2012 discharges prospectively within 30 days of the date of the fiscal intermediary's or MAC's low-volume status determination.

F. Indirect Medical Education (IME) Adjustment (§ 412.105)

1. Background

Section 1886(d)(5)(B) of the Act provides for an additional payment amount under the IPPS for hospitals that have residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at § 412.105.

Public Law 105–33 (BBA 1987) established a limit on the number of allopathic and osteopathic residents that a hospital may include in its full-time equivalent (FTE) resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit on the FTE resident count for IME purposes is effective for discharges occurring on or after October 1, 1997. Changes to the policies regarding counting residents for both IME and direct GME payment purposes as a result of the implementation of sections 5503 through 5506 of the Affordable Care Act were issued in a final rule published in the **Federal Register** on November 24, 2010 (75 FR 72133).

2. IME Adjustment Factor for FY 2012

The IME adjustment to the MS–DRG payment is based in part on the applicable IME adjustment factor. The IME adjustment factor is calculated by using a hospital's ratio of residents to beds, which is represented as *r,* and a formula multiplier, which is represented as *c,* in the following equation: $c \times [\{1 + r\}^{.405} - 1]$. The formula is traditionally described in terms of a certain percentage increase in payment for every 10-percent increase in the resident-to-bed ratio.

Section 502(a) of Public Law 108–173 modified the formula multiplier *(c)* to be used in the calculation of the IME adjustment. Prior to the enactment of Public Law 108–173, the formula multiplier was fixed at 1.35 for discharges occurring during FY 2003 and thereafter. In the FY 2005 IPPS final rule, we announced the schedule of formula multipliers to be used in the calculation of the IME adjustment and incorporated the schedule in our regulations at § 412.105(d)(3)(viii) through (d)(3)(xii). Section 502(a) modified the formula multiplier beginning midway through FY 2004 and provided for a new schedule of formula multipliers for FYs 2005 and thereafter as follows:

- For discharges occurring on or after April 1, 2004, and before October 1, 2004, the formula multiplier is 1.47.
- For discharges occurring during FY 2005, the formula multiplier is 1.42.
- For discharges occurring during FY 2006, the formula multiplier is 1.37.
- For discharges occurring during FY 2007, the formula multiplier is 1.32.
- For discharges occurring during FY 2008 and fiscal years thereafter, the formula multiplier is 1.35.

Accordingly, for discharges occurring during FY 2012, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2012 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10-percent increase in the hospital's resident-to-bed ratio.

G. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME) (§§ 412.105 and 412.106)

1. Background

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the "Pickle method."

The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the "Medicare fraction" and the "Medicaid fraction." The Medicare fraction (also known as the "SSI fraction" or "SSI ratio") is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A (including patients who are enrolled in a Medicare Advantage (Part C) plan) and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A (including patients who are enrolled in a Medicare Advantage (Part C) plan). The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the DSH statutory references (under section 1886(d)(5)(F) of the Act) to "days" apply only to hospital acute care inpatient days. Regulations located at § 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

In section IV.G.2. of this preamble, we are combining our discussion of proposed changes to the policies for counting beds in relation to the calculations for the IME adjustment at § 412.105(b) and the DSH payment adjustment at § 412.106(a)(1)(i) and for counting patient days for purposes of the DSH payment adjustment at § 412.106(a)(1)(ii).

2. Proposed Policy Change Relating to the Exclusion of Hospice Beds and Patient Days From the Medicare DSH Calculation

a. Background

As discussed in the FY 2004 IPPS final rule (68 FR 45415 through 45420), when determining a hospital's Medicare DSH payment, our policy is to include patient days in hospital units or wards that would be directly included in determining the allowable costs of inpatient hospital care payable under the IPPS on the Medicare cost report. Under this policy, CMS uses the level of care generally provided in such a unit or ward as a proxy for determining the level of care provided to a particular

patient on a particular day within that unit. As stated in the FY 2004 IPPS final rule, our policy is "not intended to focus on the level or type of care provided to individual patients in a unit, but rather on the level and type of care provided in the unit as a whole." (68 FR 45417) In the FY 2005 IPPS final rule, we amended this policy to specifically exclude observation and swing days from the patient day count. In this proposed rule, we are proposing to establish an additional exclusion with respect to counting bed days and patient days for patients receiving hospice services in an inpatient setting of a hospital.

b. Hospice Inpatient Services

Section 1861(dd)(1) of the Act defines hospice care to include a limited set of "items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician and by the medical director." Among those items and services specified under section 1861(dd)(1)(G) of the Act is "short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days." Based on these statutory definitions of hospice care, the Secretary, through regulation at § 418.302, has grouped hospice care services into four categories for payment purposes. Two of these payment categories describe hospice services in an inpatient setting: inpatient respite care day and general inpatient care day.

Section 418.302(b)(3) of the regulations defines an inpatient respite care day as "a day on which the individual who has elected hospice care receives care in an approved facility on a short-term basis for respite." Section 40.2.2 of Chapter 9 of the Medicare Benefit Policy Manual (*https://www.cms.gov/manuals/Downloads/bp102c09.pdf*) further describes an inpatient respite care day as a short-term inpatient day provided only when necessary to relieve family members or other caregivers caring for the individual at home. Under the Act, inpatient respite care is limited to 5 consecutive days for a given stay. Similarly, the regulations at § 418.302(b)(4) describe a general inpatient care day as "a day on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings."

Section 40.1.5 of Chapter 9 of the Medicare Benefit Policy Manual provides that general inpatient care is appropriate when care for pain control or acute or chronic symptom management cannot feasibly be provided in another setting. This section of the Medicare Benefit Policy Manual further states that such care is "not equivalent to a hospital level of care." That hospice care is not hospital level care is further supported by the provision at § 418.202(e), which provides that general inpatient care and inpatient respite care hospice services can be "provided in a participating hospice inpatient unit, or a participating hospital or [skilled nursing facility], that additionally meets the standards in § 418.202(a) and (e) regarding staffing and patient areas * * * [and] must conform to the [hospice provider's] written plan of care."

Furthermore, hospice services provided in an inpatient hospital setting are not payable under the IPPS. Rather, at this time, these services are payable under two of the four prospectively determined all-inclusive categories of care under the hospice payment system. In the FY 2004 IPPS final rule (68 FR 45418), we stated that we believed it "reasonable to interpret the phrase 'hospital's patient days,' to mean only the hospital's inpatient days at a level of care that would be covered under the IPPS as a means to determine an IPPS payment adjustment." In that rule, we acknowledged that it would be "administratively inefficient and impracticable" to calculate a hospital' inpatient days based on a determination of whether a particular patient in a particular inpatient bed for a particular stay is receiving a level of care that would be covered under the IPPS (68 FR 45418). Accordingly, we adopted a policy under which we use the level of care that is generally provided in particular units or wards as a proxy for determining whether the care provided to a particular patient is of a type that would be covered under the IPPS. However, we have recognized exceptions to this policy for certain categories of nonacute care, even if that care is provided in an acute care unit.

Therefore, we are proposing to revise § 412.106(a)(1)(ii) to exclude patient days associated with hospice patients receiving inpatient hospice services in an inpatient hospital setting from the Medicare and Medicaid fractions of the DPP. We also are proposing to amend our cost reporting instructions accordingly. Our proposal to exclude hospice inpatient days is analogous to our decision in the FY 2005 IPPS final rule to exclude observation and swing-bed days from the Medicare and Medicaid fractions of the DPP. In that rule, we stated that our policies to exclude observation days and swing-bed days from the count of patient days "stem from the fact that although the services are provided in beds that would otherwise be available to provide an IPPS level of services, these days are not payable under the IPPS * * *" (69 FR 49097). Similarly, our proposal to exclude inpatient hospice days stems from the fact that these days are not acute care services generally payable under the IPPS.

We note that, on rare occasions, patients receiving care under a third payment category, routine home care, may also receive services in an inpatient hospital setting. Unlike inpatient respite care or general inpatient services, routine home care services are not intended to be provided in a hospital setting. For the same reasons stated above, such days should also be excluded from the Medicare and Medicaid fractions of the DPP.

We also are proposing to exclude from the hospital's bed count days associated with hospice patients who receive inpatient hospice services in the hospital for purposes of both the IME payment adjustment and the DSH payment adjustment. The rules for counting hospital beds for the purposes of the IME adjustment are codified in the IME regulations at § 412.105(b), which is cross-referenced in § 412.106(a)(1)(i) for purposes of the DSH payment adjustment. Our bed counting policy is to include bed days available for IPPS-level acute care hospital services. Inpatient hospice services provided in an acute unit or ward are occasional, alternative uses of acute inpatient beds that would otherwise be considered available for IPPS-level acute care hospital services (as long as other criteria for a bed to be considered as an available bed are met under § 412.105(b)). A bed used for inpatient hospice services on a given day is not available to be used for IPPS-level services. Therefore, we are proposing to revise § 412.105(b)(4) to state that such hospice days are excluded from the counts of available beds for purposes of the IME payment adjustment. Because the same rules govern the counting of available beds for purposes of the DSH payment

adjustment under § 412.106(a)(1)(i), hospice days will also be excluded from the count of available beds for purposes of the DSH payment adjustment.

We note that there is a circumstance in which a hospital will provide IPPS-level acute care hospital services to a hospice patient for which it would receive payment under the IPPS. This occurs when a Medicare beneficiary receiving hospice care under his or her hospice benefit requires acute care hospital services to treat a condition unrelated to his or her hospice plan of care. For example, an individual who has elected the hospice benefit could be treated in the inpatient hospital setting for a broken bone that is unrelated to his or her terminal illness. Under these circumstances, the patient is receiving acute care hospital services of the sort payable under the IPPS. As such, consistent with § 412.106(a)(ii), we are not proposing to exclude these patient days from the Medicare and Medicaid fractions of the DPP or from the count of available beds under § 412.105(b)(4) and § 412.106(a)(1)(i).

We further note that hospitals may have hospice units that are separate and distinct from their acute care inpatient units. Under existing regulations at § 412.105(b)(3) and § 412.106(a)(ii)(A), services provided in distinct nonacute inpatient units are excluded from the patient day and bed day count. Our proposal with respect to inpatient hospice services does not change or affect this policy.

In summary, we are proposing to exclude inpatient hospice days from the patient day count in § 412.106(a)(1)(ii) (for DSH) and the bed day count at § 412.105(b) (for IME) and at § 412.106(a)(1)(i) (for DSH).

H. Medicare-Dependent, Small Rural Hospitals (MDHs) (§ 412.108)

1. Background

Under the IPPS, separate special payment protections are provided to a Medicare-dependent, small rural hospital (MDH). MDHs are paid based on the higher of the Federal rate for their hospital inpatient services or a blended rate based in part on the Federal rate and in part on the MDH's hospital-specific rate. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges either in its 1987 cost reporting year or in two of its most recent three settled Medicare cost reporting years). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be classified as an MDH.

Although MDHs are paid under an adjusted payment methodology, they are still IPPS hospitals paid under section 1886(d) of the Act. Like all IPPS hospitals paid under section 1886(d) of the Act, MDHs are paid for their discharges based on the DRG weights calculated under section 1886(d)(4) of the Act.

Through and including FY 2006, under section 1886(d)(5)(G) of the Act, MDHs are paid based on the Federal rate or, if higher, the Federal rate plus 50 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate based on the hospital's FY 1982 or FY 1987 costs per discharge, whichever of these hospital-specific rates is higher. Section 5003(b) of Public Law 109–171 (DRA 2005) amended section 1886(d)(5)(G) of the Act to provide that, for discharges occurring on or after October 1, 2006, MDHs are paid based on the Federal rate or, if higher, the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever of these hospital-specific rates is highest.

For each cost reporting period, the fiscal intermediary or MAC determines which of the payment options will yield the highest aggregate payment. Interim payments are automatically made at the highest rate using the best data available at the time the fiscal intermediary or MAC makes the determination. However, it may not be possible for the fiscal intermediary or MAC to determine in advance precisely which of the rates will yield the highest aggregate payment by year's end. In many instances, it is not possible to accurately forecast the outlier payments, the amount of the DSH adjustment or the IME adjustment, all of which are applicable only to payments based on the Federal rate and not to payments based on the hospital-specific rate. The fiscal intermediary or MAC makes a final adjustment at the settlement of the cost report after it determines precisely which of the payment rates would yield the highest aggregate payment to the hospital.

If a hospital disagrees with the fiscal intermediary's or the MAC's determination regarding the final amount of program payment to which it is entitled, it has the right to appeal the determination in accordance with the procedures set forth in 42 CFR Part 405, Subpart R, which govern provider payment determinations and appeals.

2. Extension of the MDH Program

As we discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50286 and 50287), section 3124 of the Affordable Care Act extended the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges occurring before October 1, 2012). Under prior law, as specified in section 5003(a) of Public Law 109–171 (DRA 2005), the MDH program was to be in effect through the end of FY 2011 only. Section 3124(a) of the Affordable Care Act amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to extend the MDH program and payment methodology from the end of FY 2011 to the end of FY 2012, by striking "October 1, 2011" and inserting "October 1, 2012". Section 3124(b) of the Affordable Care Act also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act. Section 3124(b)(2) of the Affordable Care Act also amended section 13501(e)(2) of OBRA 1993 to extend the provision permitting hospitals to decline reclassification as an MDH through FY 2012. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287 and 50414), we amended the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the statutory extension of the MDH program through FY 2012. We are not proposing any additional changes to this regulatory text for FY 2012.

I. Certified Registered Nurse Anesthetist (CRNA) Services Furnished in Rural Hospitals and CAHs (§ 412.113)

Section 2312 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) provided for reimbursement to hospitals on a reasonable cost basis for the costs that hospitals incur in connection with the services of certified registered nurse anesthetists (CRNAs). Section 2312(c) provided that pass-through payment of CRNA costs was effective for cost reporting periods beginning on or after October 1, 1984, and before October 1, 1987. Section 9320 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509) (which established a fee schedule for the services of nurse anesthetists) amended section 2312(c) of Public Law 98–369 by extending the CRNA pass-through provision through cost reporting periods beginning before January 1, 1989. In addition, Public Law 99–509 amended section 1861 of the Act to add a new subsection (bb), which provides that CRNA services include anesthesia services and related care furnished by a CRNA. Section 608 of the Family Support Act of 1988 (Pub. L.

100–485) extended pass-through payments for CRNA services through 1991 and amended section 9320 of Public Law 99–509 by including language referring to eligibility for pass-through payments for CRNA services if the facility is "* * *a hospital located in a rural area (as defined for purposes of section 1886(d) of the Social Security Act)." Reasonable cost-based payment for CRNA services was extended indefinitely by section 6132 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239).

Section 1886(d) of the Act defines "rural" as any area outside an urban area. This definition of "rural" was in effect when Public Law 100–485 was implemented. In 1999, the Balanced Budget Refinement Act (Pub. L. 106–113) amended section 1886(d)(8) of the Act by adding a new subparagraph (E), which permits a hospital physically located in an urban area to apply for reclassification to be treated as rural. In addition, Public Law 106–113 made a corresponding change to section 1820(c)(2)(B)(i) of the Act, which specifies the rural location requirement for CAH designation, by adding the phrase "or is treated as being located in a rural area pursuant to section 1886(d)(8)(E)."

The regulations implementing pass-through payments for anesthesia services and related care furnished by qualified nonphysician anesthetists employed by a hospital or CAH, including CRNAs, are located at § 412.113(c). In the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24010), we proposed to revise § 412.113(c)(2)(i)(A) to state that, effective for cost reporting periods beginning on or after October 1, 2010, CAHs and hospitals that have reclassified pursuant to section 1886(d)(8)(E) of the Act and § 412.103 of the regulations also are rural for purposes of section 1886(d) of the Act and, therefore, are eligible to be paid based on reasonable cost for anesthesia services and related care furnished by a qualified nonphysician anesthetist.

After consideration of the public comments, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303), we adopted a policy that would allow otherwise eligible critical access hospitals (CAHs) or hospitals, that have reclassified from urban to rural status under section 1886(d)(8)(E) of the Act and 42 CFR 412.103, to receive reasonable cost payments for anesthesia services and related care furnished by qualified nonphysician anesthetists (also referred to in this section as CRNA pass-through payments), effective for cost reporting periods beginning on or after October 1, 2010. After the issuance of the final rule, we received an inquiry from a public commenter who indicated that CMS had misunderstood its submitted comment on the FY 2011 IPPS/LTCH PPS proposed rule in which the commenter stated that the policy should be effective on the basis of a calendar year, not a cost reporting period, since as a rule a hospital can only begin receiving CRNA pass-through payments at the beginning of a calendar year. Our response to this public comment in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303) indicated that it was unnecessary to modify the effective date in the final rule because "if the provision is effective for cost reporting periods beginning on or after October 1, 2010, it will also be in effect for the calendar year beginning January 1, 2011." While this statement was accurate, it did not take into account that if a hospital's cost reporting period begins on or after January 1, 2011, the hospital would be ineligible to receive CRNA pass-through payments until the beginning of the next calendar year, on January 1, 2012. Under the finalized policy in the FY 2011 IPPS/LTCH PPS final rule, hospitals reclassifying from urban to rural areas with cost reporting periods beginning between October 1, 2010, and December 31, 2010, would be able to first receive CRNA pass-through payments effective January 1, 2011, while hospitals with cost reporting periods beginning on or after January 1, 2011, would not be able to receive CRNA pass-through payments until one year later on January 1, 2012.

In an interim final rule with comment period included in the **Federal Register** on November 24, 2010 (75 FR 72256), we stated that our intention in the FY 2011 IPPS/LTCH PPS final rule was not to make the provision for CRNA pass-through payment for anesthesia services and related care furnished by nonphysician anesthetists effective January 1, 2011, for some hospitals and CAHs and January 1, 2012, for other hospitals and CAHs. We stated our belief that the provision would be more equitable if it had a uniform effective date for all eligible hospitals and CAHs. While we considered changing the effective date to January 1, 2011, for all hospitals and CAHs to begin receiving CRNA pass-through payments under this provision, we noted that our regulations at 42 CFR 412.113(c)(2)(iii) state that the hospital or CAH must demonstrate to its fiscal intermediary prior to the start of the calendar year that it meets the requirements for receiving CRNA pass-through payments. For this reason, we stated our belief that the best option was to adopt an effective date of December 2, 2010, for all hospitals and CAHs, which we provided for in the interim final rule with comment period. With an effective date of December 2, 2010, all hospitals and CAHs regardless of their specific fiscal year beginning date were provided the opportunity to demonstrate prior to January 1, 2011, that they met the requirements for receiving CRNA pass-through payments beginning January 1, 2011. In the interim final rule with comment period, we amended the regulations at § 412.113(c)(2)(i)(A) to provide for an effective date of December 2, 2010, for all eligible hospitals and CAHs to receive CRNA pass-through payments for anesthesia services and related care furnished by qualified nonphysician anesthetists.

We intend to respond to public comments received on the interim final rule with comment period and will adopt our final policy in the FY 2012 IPPS/LTCH PPS final rule.

J. Additional Payments for Qualifying Hospitals With Lowest per Enrollee Medicare Spending

1. Background

Section 1109 of the Affordable Care Act requires additional payments for FYs 2011 and 2012 for "qualifying hospitals." Section 1109(d) defines a "qualifying hospital" as a "subsection (d) hospital * * * that is located in a county that ranks, based upon its ranking in age, sex and race adjusted spending for benefits under parts A and B * * * per enrollee within the lowest quartile of such counties in the United States." Therefore, a "qualifying hospital" is one that meets the following conditions: (1) It is a "subsection (d) hospital" as defined in section 1886(d)(1)(B) of the Act; and (2) it is located in a county that ranks within the lowest quartile of counties based upon its spending for benefits under Medicare Part A and Part B per enrollee adjusted for age, sex, and race. Section 1109(b) of the Affordable Care Act makes available $400 million to qualifying hospitals for FY 2011 and FY 2012. Section 1109(c) of the Affordable Care Act requires the $400 million to be divided among each qualifying hospital in proportion to the ratio of the individual qualifying hospital's FY 2009 IPPS operating hospital payments to the sum of total FY 2009 IPPS operating hospital payments made to all qualifying hospitals.

Section 1109 is one of several provisions in the Affordable Care Act that addresses concerns about how Medicare makes adjustments for geographic differences in the cost of

providing services and geographic variation in the volume and intensity of health care spending. Some other provisions in the Affordable Care Act that relate to concerns about geographic variation in Medicare payments include:

- Section 3102(a), which provides a floor of 1.0 on the physician fee schedule work geographic practice cost index (GPCI) through the end of CY 2010 (later extended by the Medicare and Medicaid Extension Act of 2010 through the end of CY 2011);
- Section 3102(b), as amended by section 1108 of the Affordable Care Act, which requires that only one-half of the relative cost differences in employee wages and office rents be reflected in the practice expense GPCIs in 2010 and 2011;
- Section 10324, which provides for a floor on the wage index and the practice expense GPCI in frontier States (defined as 50 percent or more of the counties in the State having a population density of less than six people per square mile).

These provisions provide temporary adjustments in payments while other initiatives are underway to evaluate geographic adjustment factors that are used in Medicare's payment systems. For instance, section 3101 of the Affordable Care Act requires the Secretary, not later than January 1, 2012, to make appropriate adjustments to the practice expense GPCI considering alternative data sources such as the American Community Survey for the nonphysician employee portion of the GPCI. Section 3137 of the Affordable Care Act requires the Secretary to submit to Congress a report that includes a plan to reform the hospital wage index system under section 1886 of the Act by December 31, 2011. In addition to these provisions, the Secretary has contracted with the Institute of Medicine (IOM) to study the hospital wage index and the physician fee schedule GPCI. The IOM's first report to CMS is due in May 2011 and will provide an evaluation and assessment of:

(1) The empirical validity of the adjustment factors (the hospital wage index and physician fee schedule GPCI);

(2) The methodology used to determine the adjustment factors;

(3) Measures used for the adjustment factors, taking into account—

- Timeliness of data and frequency of revisions to such data;
- Sources of data and the degree to which such data are representative of costs; and
- Operational costs of providers who participate in Medicare.

The report will include recommendations for the Secretary to consider. We are looking forward to receiving IOM's report and acting expeditiously on its recommendations to improve Medicare's payment systems and better adjust for geographic differences in the cost of hospital labor as well as the cost of operating a physician practice.

2. Methodology for Identifying Qualifying Hospitals and Eligible Counties

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303 through 50342), we finalized our methodology for distributing the $400 million to qualifying hospitals located in the lowest quartile of counties in per enrollee Medicare spending. First, we provided our methodology for determining the bottom quartile of counties with the lowest Medicare Part A and Part B spending adjusted by age, sex, and race for the purpose of disbursing the available $400 million. We developed an adjustment model by age, sex, and race, as required under the provisions of section 1109. We then applied this adjustment to the county Medicare Part A and Part B spending data to account for the demographics of the Medicare beneficiaries in those counties. After those adjustments were applied, we determined the Medicare Part A and Part B spending by county per enrollee. As we explained in the final rule, our methodology for determining the Medicare Part A and Part B spending per enrollee by county adjusted for age, sex, and race is similar to the methodology we use to calculate risk adjustment models for Medicare Advantage (MA) ratesetting. For more information on the methodology we used to calculate the county Medicare per enrollee spending rates, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50303 through 75 FR 50307).

In addition, in the FY 2011 IPPS/LTCH PPS final rule, we developed a methodology to identify the qualifying hospitals located in each of the eligible counties. As we stated earlier, section 1109 defines a qualifying hospital is a "subsection (d) hospital" (as defined for purposes of section 1886(d) of the Act) that is "located in" an eligible county. A subsection (d) hospital is defined in section 1886(d)(1)(B) of the Act, in part, as a "hospital located in one of the 50 States or the District of Columbia." Therefore, we excluded Puerto Rico hospitals and CAHs from the provisions of section 1109 because they do not meet the definition of a "subsection (d) hospital."

In the FY 2011 IPPS/LTCH PPS final rule, we identified "qualifying hospitals" based on their Medicare provider number (now referred to as the "CMS certification number" (CCN)) because this number is used by hospitals to identify themselves on their Medicare cost reports. We also provided that, in order to meet the definition of a "qualifying hospital," the hospital, as identified by its CCN, must: (1) Have existed as a subsection (d) hospital as of April 1, 2010; (2) be geographically located in an eligible county; and (3) have received IPPS operating payments (in accordance with section 1886(d)) of the Act) under its CCN in FY 2009. We used the Online Survey, Certification and Reporting (OSCAR) database to determine a hospital's county location associated with that CCN. We also specified that the address listed for a hospital's CCN must be currently located in a qualifying county in order for a hospital to meet the definition of a "qualifying hospital." For more information on how we identified the qualifying hospitals, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50307 and 50308). We note that we are proposing to clarify the application of our definition in section IV.J.4. of this preamble.

3. Determination of Annual Payment Amounts

The third step in the implementation of section 1109 of the Affordable Care Act required that we determine the payment amount that each qualifying hospital would receive. Specifically, section 1109(c) of the Affordable Care Act required that the payment amount for a qualifying hospital be determined "in proportion to the portion of the amount of the aggregate payments under section 1886(d) of the Social Security Act to the hospital for fiscal year 2009 bears to the sum of all such payments to all qualifying hospitals for such fiscal year." As specified in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50310 through 50312), we determined that a qualifying hospital's payment amount will be based on the proportion of its IPPS operating payments made in FY 2009 under section 1886(d) of the Act relative to the total IPPS operating payments made to all qualifying hospitals in FY 2009 under section 1886(d) of the Act. The FY 2009 IPPS operating payments made under section 1886(d) of the Act includes DRG and wage-adjusted payments made under the IPPS standardized amount with add-on payments for operating DSH, operating IME, operating outliers, and new technology (collectively referred to in this preamble as the IPPS operating payment amount). We used the March 2010 update of the FY 2009 MedPAR

hospital inpatient claims data to determine the IPPS operating payment amounts for each qualifying hospital in order to calculate the proportion of money that each qualifying hospital would receive under this provision. For more information on the methodology we used to calculate the payment determinations, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 30310 through 75 FR 50312).

4. Eligible Counties and Qualifying Hospitals

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50312 through 50342), we published the list of eligible counties, that is, the lowest quartile of counties with Medicare Part A and Part B spending per enrollee adjusted for age, sex, and race, the qualifying hospitals located in those counties, and the qualifying hospitals' payment weighting factors, for purposes of making payments under section 1109 for FY 2011 and FY 2012. We identified 3,142 counties in the United States. Therefore, there are 786 eligible counties (rounded from 785.5 eligible counties). Of those 786 eligible counties, there are only 273 counties in which qualifying hospitals are located, using the methodology that we finalized in the FY 2011 IPPS/LTCH PPS final rule. Using CCNs, we identified 416 IPPS hospitals that are currently located in those eligible counties and that received IPPS operating payments in FY 2009.

In response to public comments on the FY 2011 IPPS/LTCH PPS proposed rule, in the FY 2011 IPPS/LTCH PPS final rule, we corrected the list of eligible counties by replacing two counties on our list of eligible counties (adding Crooks County, OR and Bottineu County, ND). However, we did not identify any qualifying hospitals located in those two eligible counties. Therefore, we provided the public an opportunity to notify CMS by August 30, 2010, if there were any qualifying IPPS hospitals located in either of the two newly added counties. We stated that if we added qualifying hospitals in these counties as a result of accurate notification from the public, we would publish a revised list of qualifying hospitals and their payment weighting factors on the CMS Web site after August 30, 2010. We did not receive any public comments that there were qualifying hospitals located in Crooks County, OR or Bottineu County, ND. Therefore, the list of eligible counties and qualifying hospitals that was finalized in Tables 1 and 2 in the FY 2011 IPPS/LTCH PPS final rule remained valid for distribution of payments under section 1109 for FY 2011 and FY 2012.

In auditing our determination of qualifying hospitals prior to the distribution of payments for FY 2011, we found that the following providers on the list of qualifying hospitals which we finalized in the FY 2011 IPPS/LTCH PPS final rule were not subsection (d) hospitals in FY 2011:

CMS Certification Number	Provider Name
110231	Landmark Hospital of Athens LLC
130024	Bonner General Hospital
130069	SW Idaho Advanced Care
130070	Complex Care Hospital of Idaho
160156	Continuing Care Hospital at St. Luke's
250112	Calhoun Health Services
260221	Select Specialty Hospital - Springfield Inc.
270002	Holy Rosary Healthcare
320088	Advanced Care of South New Mexico
330010	Amsterdam Memorial Hospital
500143	Providence St. Peter Chemical Dependency Center

Because these providers were not subsection (d) hospitals in FY 2011, the statute precludes them from being qualifying hospitals eligible to receive section 1109 payments for FY 2011. We are proposing to clarify in this proposed rule that, in applying our definition of qualifying hospitals for making payments under section 1109 of the Affordable Care Act, these 11 providers (and other providers that do not meet the statutory definition) are not qualifying hospitals and, therefore, should be removed from the list of qualifying hospitals. Furthermore, we are proposing to clarify that, in order to meet the definition of "qualifying hospital" under section 1109 for FY 2012, a hospital that is on the list of qualifying hospitals in this proposed rule must meet the statutory criteria of a "qualifying hospital" for some portion of FY 2012 (a hospital must be a subsection (d) hospital for some part of FY 2012).

In addition, we note that, prior to the issuance of the FY 2012 final rule and prior to making section 1109 payments for FY 2012, we intend to review providers' status vis-à-vis the statutory definition of qualifying hospital. Accordingly, we note that, in the FY 2012 final rule and again prior to distribution of section 1109 payments for FY 2012, we will update the list of qualifying hospitals and payment weighting factors based on these findings. In addition to the opportunity to submit comments on this proposed rule, we are proposing to provide hospitals an opportunity after the FY 2012 IPPS rulemaking cycle to notify CMS whether any qualifying hospitals removed from the list have been removed in error and to notify CMS if a hospital is on the list of qualifying hospitals and will not be a qualifying hospital (for example, a subsection (d) hospital) for any or all part of FY 2012. The public may submit input on these two topics via e-mail to Nisha Bhat, *nisha.bhat@cms.hhs.gov.* All information, including relevant

documentation, must be received by November 1, 2011.

5. Payment Determinations and Distributions for FY 2011 and FY 2012

Under section 1109(b) of the Affordable Care Act, the total pool of payments available to qualifying hospitals for FY 2011 and FY 2012 is $400 million. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50308 through 50310), we stated that we would distribute $150 million for FY 2011 and $250 million for FY 2012. We stated that we would distribute payments to the qualifying hospitals through an annual one-time payment during each of FY 2011 and FY 2012 through their Medicare contractor (fiscal intermediary or MAC). We instructed qualifying hospitals to report these additional payments on their Medicare hospital cost report corresponding to the appropriate cost reporting period that the hospitals receive the payments and that hospitals should report these payments on the "Other adjustment" line on Worksheet E, Part A of the Medicare hospital cost report Form 2552. We noted that we require these payments to be reported on the cost report for tracking purposes only and that these additional payments will not be adjusted or settled by the fiscal intermediary or MAC on the cost report.

At the time of the issuance of this FY 2012 proposed rule, we have not yet made the payments to the qualifying hospitals for FY 2011. As we stated in the FY 2011 IPPS/LTCH PPS final rule, we will make the FY 2011 payments during FY 2011 (that is, by September 30, 2011). However, in this proposed rule, we are notifying the public that we intend to change the method we will use to distribute the payment for FY 2011 and FY 2012, in order to ease the reporting burden on hospitals. Rather than making a one-time annual payment to the qualifying hospitals through their Medicare contractor using the Medicare cost report, we plan to make payments to the qualifying hospitals through a one-time annual payment made by one Medicare contractor who would directly pay all of the qualifying hospitals. We will send each qualifying hospital a letter stating the specifics of how the hospital will receive its payments. Because these one-time annual payments would be made through a special process outside of the scope of normal payments by their Medicare contractor, the hospitals' Medicare contractor would no longer need to track the payment amounts made to the hospitals under this provision. We believe this will simplify and expedite the payment process so that one Medicare contractor is responsible for overseeing the distribution of payments. In addition, this simplified process will ease the administrative burden within CMS to track that payments have been properly made to the qualifying hospitals. In addition, the burden to hospitals is reduced because hospitals would no longer have to report these additional payments on their Medicare hospital cost report corresponding to the appropriate cost reporting period for which the hospitals receive payments in FY 2011 or FY 2012 (as we instructed in the FY 2011 IPPS/LTCH PPS final rule and note above).

In the FY 2011 IPPS/LTCH PPS final rule, we also stated that we would make only one determination of eligible counties and qualifying hospitals for FY 2011 and FY 2012, with the caveat that we would accept additional public input on the limited issue of whether there are any qualifying hospitals in the two newly identified eligible counties. As we stated earlier, we did not receive any public input on qualifying hospitals for the two newly identified eligible counties. However, as we describe above, 11 hospitals that were included on the list of qualifying hospitals do not meet the statutory criteria in section 1109 of the Affordable Care Act. Therefore, we are proposing to revise our list of qualifying hospitals and their payment weighting factors finalized in the FY 2011 IPPS/LTCH PPS final rule to exclude these 11 providers. As explained in the FY 2011 IPPS/LTCH PPS final rule, we finalized in that rule (to the best of our ability) the list of eligible counties and qualifying hospitals once for ease of implementation of the section 1109 provision and to allow hospitals to plan their budgets accordingly. The proposed revision of our determination to exclude these 11 providers will result in changes to the payment weighting factors. We are proposing to update the payment weighting factors accordingly. Therefore, we are proposing to distribute the remaining $250 million in FY 2012 to those qualifying hospitals proposed in this proposed rule based on payment weighting factors proposed in this proposed rule. In addition, in order to distribute the section 1109 payments for FY 2011 in as timely a manner as possible, we intend to make preliminary section 1109 payments for FY 2011 using this proposed list of qualifying providers and payment weighting factors using the payment method described above. If additional hospitals are deleted from the proposed list of qualifying hospitals for FY 2011 because they do not meet the statutory criteria, the payment weighting factors would need additional revision. If this situation occurs, we are proposing to further amend the payment weighting factors for payments to be made in FY 2012 so that each qualifying hospital receives its appropriate share of the total $400 million.

We refer readers to the CMS Web site at: *http://www.cms.gov/AcuteInpatientPPS/TopOfPage* for the tables listed below. The tables are included collectively as the "Section 1109 Files" for the FY 2012 IPPS/LTCH proposed rule.

- The final list of eligible counties that was published in the FY 2011 IPPS/LTCH PPS final rule. We note that we are not updating this table.
- The proposed list of qualifying hospitals, location, and payment weighting factors (based on the March 2010 update of the FY 2009 MedPAR); based on the clarifications proposed above.
- The distribution of the $400 million for FY 2011 and FY 2012 by State based on the proposed list of qualifying hospitals, location, and payment weighting factors.

We note that the Web address for this Web site is effective as of the date of publication of this proposed rule and that, in the future, these tables may be archived to the Web site at: *http://www.cms.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

K. Proposed Changes in the Inpatient Hospital Update

1. FY 2012 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient operating costs by a factor called the "applicable percentage increase." Prior to enactment of the Affordable Care Act, section 1886(b)(3)(B)(i)(XX) of the Act set the applicable percentage increase equal to the rate-of-increase in the hospital market basket for subsection (d) hospitals (hereafter referred to as "IPPS hospitals") in all areas, subject to the hospital submitting quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act. For hospitals that did not provide these data, the update was equal to the market basket percentage increase less an additional 2.0 percentage points. The update for the hospital-specific rates for SCHs and MDHs is set by section 1886(b)(3)(B)(iv) of the Act as discussed further below.

As discussed below in section IV.K.3. of this preamble, section 1886(b)(3)(B)

of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2012 as equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas (which is currently based on the first quarter 2011 forecast of the FY 2006-based IPPS market basket), subject to a reduction of 2.0 percentage points if the hospital fails to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.1 percentage point. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2012 adjustment of 0.1 percentage point may result in the applicable percentage increase being less than zero.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing an MFP adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.2 percent, which is calculated as described below in section IV.K.3. of this preamble, based on IHS Global Insight, Inc.'s (IGI's) first quarter 2011 forecast.

Consistent with current law, and based on IGI's first quarter 2011 forecast of the FY 2012 market basket increase, we are proposing an applicable percentage increase to the FY 2012 operating standardized amount of 1.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for economy-wide productivity and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance with our rules. For hospitals that do not submit quality data, we are proposing an applicable percentage increase to the operating standardized amount of −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent, less 2.0 percentage points for failure to submit quality data, less an adjustment of 1.2 percentage points for economy-wide productivity, and less an additional adjustment of 0.1 percentage point).

We are proposing to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law. Specifically, in accordance with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are proposing to add a new paragraph (iv) to § 412.64(d)(1) to set the applicable percentage increase to the FY 2012 operating standardized amount as the percentage increase in the market basket index, subject to a reduction of 2.0 percentage points if the hospital fails to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to a multifactor productivity adjustment and, lastly, subject to the additional reduction of 0.1 percentage point.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital specific rates for SCHs and MDHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, we are proposing an update to the hospital-specific rates applicable to SCHs and MDHs of 1.5 percent for hospitals that submit quality data or −0.5 percent for hospitals that fail to submit quality data. For FY 2012, the regulations in §§ 412.73(c)(16), 412.75(d), 412.77(e), 412.78(e), and 412.79(d) already contain provisions that set the update factor for SCHs and MDHs equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, we are not proposing to make further changes to these five regulatory provisions to reflect the FY 2012 update factor for SCHs and MDHs.

2. FY 2012 Puerto Rico Hospital Update

Puerto Rico hospitals are paid a blended rate for their inpatient operating costs based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 1886(d)(9)(C)(i) of the Act is the basis for determining the applicable percentage increase applied to the Puerto Rico-specific standardized amount. Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act, which states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 1.5 percent. For FY 2012, under the authority of section 1886(d)(9)(C)(i) of the Act, as amended by section 401(c) of Public Law 108–173, we are proposing to revise the existing regulations at § 412.211(c) to set the update factor for the Puerto Rico-specific operating standardized amount equal to the update factor applied to the national standardized amount for all IPPS hospitals.

3. Productivity Adjustment

Section 3401(a) of the Affordable Care Act amends section 1886(b)(3)(B) of the Act to require certain adjustments to the "applicable percentage increase" to the operating IPPS. One such change is to require that, in FY 2012 (and in subsequent fiscal years), the applicable percentage increase be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period) (the "MFP adjustment"). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at: *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data.

The projection of MFP is currently produced by IHS Global Insight, Inc. (IGI), an economic forecasting firm. In order to generate a forecast of MFP, IGI replicated the MFP measure calculated by the BLS using a series of proxy variables derived from its U.S. macroeconomic models. These models take into account a broad range of factors that influence the total U.S.

economy. IGI forecasts the underlying proxy components such as Gross Domestic Product (GDP), capital, and labor inputs required to estimate MFP and then combines those projections according to the BLS methodology. In Table IV.K.1 below, we identify each of the major MFP component series employed by the BLS to measure MFP. We also provide the corresponding concepts forecasted by IGI and determined by IGI and CMS to be the best available proxies for the BLS series.

TABLE IV.K.1.—MULTIFACTOR PRODUCTIVITY COMPONENT SERIES EMPLOYED BY THE BUREAU OF LABOR STATISTICS AND IHS GLOBAL INSIGHT

BLS Series	IGI Series
Real value-added output, constant 2005 dollars	Nonhousing, nongovernment, nonfarm real GDP, Billions of chained 2005 dollars – annual rate
Private nonfarm business sector labor input; 2005=100.00	Hours of all persons in private non-farm establishments, 2005=100.00, adjusted for labor composition effects
Aggregate capital inputs; 2005=100.00	Real effective capital stock used for full employment GDP, Billions of chained 2005 dollars

IGI found that the historical growth rates of the BLS components used to calculate MFP and the IGI components identified are consistent across all series and, therefore, suitable proxies for calculating MFP. We have included below a more detailed description of the methodology used by IGI to construct a forecast of MFP, which is aligned closely with the methodology employed by the BLS. For more information regarding the BLS method for estimating productivity, we refer readers to the BLS Web site at: *http://www.bls.gov/mfp/mprtech.pdf.*

At the time of the development of this proposed rule, the BLS had published a historical time series of private nonfarm business MFP for 1987 through 2009, with 2009 being a preliminary value. Using this historical MFP series and the IGI forecasted series, the IGI had developed a forecast of MFP for 2010 through 2021, as described below.

To create a forecast of BLS' MFP index, the forecasted annual growth rates of the "non-housing, non-government, nonfarm, real GDP," "hours of all persons in private non-farm establishments adjusted for labor composition," and "real effective capital stock" series (ranging from 2010 to 2021) are used to "grow" the levels of the "real value-added output," "private nonfarm business sector labor input," and "aggregate capital input" series published by the BLS. Projections of the "hours of all persons" measure are calculated using the difference between projections of the BLS index of output per hour and real GDP. This difference is then adjusted to account for changes in labor composition in the forecast interval.

Using these three key concepts, MFP is derived by subtracting the contribution of labor and capital inputs from output growth. However, in order to estimate MFP, we need to understand the relative contributions of labor and capital to total output growth. Therefore, two additional measures are needed to operationalize the estimation of the IGI MFP projection: Labor compensation and capital income. The sum of labor compensation and capital income represents total income. The BLS calculates labor compensation and capital income (in current dollar terms) to derive the nominal values of labor and capital inputs. IGI uses the "nongovernment total compensation" and "flow of capital services from the total private nonresidential capital stock" series as proxies for the BLS' income measures. These two proxy measures for income are divided by total income to obtain the shares of labor compensation and capital income to total income. In order to estimate labor's contribution and capital's contribution to the growth in total output, the growth rates of the proxy variables for labor and capital inputs are multiplied by their respective shares of total income. These contributions of labor and capital to output growth are subtracted from total output growth to calculate the "change in the growth rates of multifactor productivity":

*MFP = Total output growth—(labor input growth * labor compensation share) + (capital input growth * capital income share))*

The change in the growth rates (also referred to as the compound growth rates) of the IGI MFP are multiplied by 100 in order to calculate the percent change in growth rates (the percent change in growth rates are published by the BLS for its historical MFP measure). Finally, the growth rates of the IGI MFP are converted to index levels based to 2005 to be consistent with the BLS' methodology. For benchmarking purposes, the historical growth rates of IGI's proxy variables were used to estimate a historical measure of MFP, which was compared to the historical MFP estimate published by the BLS. The comparison revealed that the growth rates of the components were consistent across all series and, therefore, validated the use of the proxy variables in generating the IGI MFP projections. The resulting MFP index was then interpolated to a quarterly frequency using the Bassie method for temporal disaggregation. The Bassie technique utilizes an indicator (pattern) series for its calculations. IGI uses the index of output per hour (published by the BLS) as an indicator when interpolating the MFP index.

As described in section I. of the Addendum to this proposed rule, we are proposing to determine the IPPS market

basket percentage increase for FY 2012, which is used to determine the FY 2012 applicable percentage increase, based on the FY 2006-based IPPS market basket. The FY 2006-based IPPS market basket was finalized and adopted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43843). Section 3401(a) of the Affordable Care Act amended section 1886(b)(3)(B) of the Act in part by adding a new clause (xi) which requires that, after determining the applicable percentage increase for a fiscal year, "such percentage increase shall be reduced by the productivity adjustment described in subclause (II)" (which we refer to as the "MFP adjustment"). Section 1886(b)(3)(B)(i)(XX) of the Act establishes the applicable percentage increase for FY 2007 and each subsequent fiscal year as equal to the rate-of-increase (that is, the percentage increase) in the hospital market basket for IPPS hospitals, subject to the hospital submitting quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and to other statutory adjustments, including the productivity adjustment.

We are proposing that the MFP adjustment be subtracted from the FY 2012 operating applicable percentage increase. We are proposing that the end of the 10-year moving average of changes in the MFP should coincide with the end of the appropriate FY update period. Because the applicable percentage increase is reduced by the MFP adjustment, we believe it is appropriate for the numbers associated with both components of the calculation (the underlying market basket percentage increase used to determine the applicable percentage increase and the productivity adjustment) to line up so that changes in market conditions are aligned. Therefore, for the FY 2012 update, the MFP adjustment is calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2012. We are proposing to round the final annual adjustment to the one-tenth of one percentage point level up or down as applicable according to conventional rounding rules (that is, if the number we are rounding is followed by 5, 6, 7, 8, or 9, we would round the number up; if the number we are rounding is followed by 0, 1, 2, 3, or 4, we would round the number down).

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to base the FY 2012 market basket update used to determine the applicable percentage increase for the IPPS on the first quarter 2011 forecast of the FY 2006-based IPPS market basket, which is estimated to be 2.8 percent. This percentage increase, subject to the hospital submitting quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, is then reduced by the proposed MFP adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.2 percent, which is calculated as described above and based on IGI's first quarter 2011 forecast. We are proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the FY 2012 market basket update and MFP adjustment in the final rule. Following application of the productivity adjustment, the applicable percentage increase is then reduced by 0.1 percentage point, as required by section 1886(b)(3)(B)(xii) of the Act, as added and amended by sections 3401 and 10319(a) of the Affordable Care Act (as discussed in section I. of the Addendum to this proposed rule).

L. Additional Payments to Hospitals With High Percentage of End-Stage Renal Disease (ESRD) Discharges (§ 412.104)

Under existing regulations at § 412.104(a), we provide additional Medicare payments to a hospital for inpatient services provided to Medicare beneficiaries with end-stage renal disease (ESRD) who receive dialysis during a hospital stay if the hospital's ESRD Medicare beneficiary discharges, excluding certain MS–DRGs noted below, where the beneficiary receives dialysis during the inpatient stay, are 10 percent or more of its total Medicare discharges. These additional payments are intended to lessen the impact of the added costs for hospitals that deliver inpatient dialysis services to a high concentration of ESRD Medicare beneficiaries. The regulation provides that discharges classified into MS–DRG 652 (Renal Failure), MS–DRG 682 (Renal Failure with MCC), MS–DRG 683 (Renal Failure with CC), MS–DRG 684 (Renal Failure without CC/MCC), and MS–DRG 685 (Admit for Renal Dialysis) are excluded from the calculation of ESRD Medicare beneficiary discharges for purposes of determining a hospital's eligibility for these additional payments. We excluded these MS–DRGs because they include payment for the cost of inpatient dialysis treatments.

The current Medicare cost reporting instructions in the Provider Reimbursement Manual, Part II (PRM–II), at section 3630.1, require hospitals to enter as the denominator of the calculation on Line 5 "total Medicare discharges as reported on Worksheet S–3, Part I," excluding discharges for the dialysis MS–DRGs. As drafted, this instruction includes only discharges for beneficiaries enrolled in original fee-for-service Medicare in the denominator of the calculation. We are proposing to clarify that our policy is that the term "Medicare discharges" used in § 412.104(a) refers to discharges of all beneficiaries entitled to Medicare Part A. Discharges associated with individuals entitled to Medicare Part A include discharges of individuals receiving benefits under original Medicare, discharges of individuals whose inpatient benefits are exhausted or whose stay was not covered by Medicare, and discharges for individuals enrolled in Medicare Advantage Plans, cost contracts under section 1876 of the Act (health maintenance organizations (HMOs)) and competitive medical plans (CMPs). Consistent with this proposed clarification, these discharges would be included in the denominator of the calculation for the purpose of determining eligibility for the ESRD additional payment to hospitals. Similarly, for the numerator of this calculation, all discharges of ESRD beneficiaries who are entitled to Medicare Part A and who receive inpatient dialysis, subject to the exclusions of certain discharges classified into MS–DRGs 652, 682, 683, 684, and 685, would be included in the determination of eligibility for the additional payment to hospitals. We intend to revise the instructions under section 3630.1 of the Provider Reimbursement Manual to reflect this clarification.

M. Proposal for Changes to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

1. Background

Currently, certain pension costs may be allowable costs under Medicare to the extent such costs are related to the reasonable and necessary cost of providing patient care and represent costs actually incurred. Reasonable cost reimbursement is addressed in section 1861(v)(1)(A) of the Act. Section 1861(v)(1)(A) of the Act defines "reasonable cost," in part, as the cost actually incurred, excluding costs found to be unnecessary in the efficient delivery of needed health services. Section 1861(v)(1)(A) of the Act does not specifically address the determination of reasonable costs, but

authorizes the Secretary to promulgate regulations and principles to be applied in determining reasonable costs.

We have issued regulations implementing this provision of the Act, including 42 CFR 413.9(a), which provide that the determination of reasonable cost "must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries." In addition, § 413.9(c) requires that the provision for payment of reasonable cost of services is intended to meet the actual costs incurred in providing services. Therefore, in accordance with the statute, the regulations include two principles that help guide the determination of which expenses may be considered allowable reasonable costs that can be paid under Medicare; that is, such costs must be "related" to the care of Medicare beneficiaries, and such costs must actually be "incurred."

Consistent with these provisions, we have issued instructions in section 2142 of the Provider Reimbursement Manual, Part I (PRM–I) for determining and reporting defined benefit pension costs on the cost report for Medicare cost-finding purposes. For Medicare wage index purposes, the cost reporting instructions in section 3605.2 of the Provider Reimbursement Manual, Part II (PRM–II) for Worksheet S–3, Part II, Lines 13 through 20, require hospitals to comply with the requirements in section 2142 of the PRM–I.

Specifically, section 2142.5 of the PRM–I defines the current period liability for pension cost (that is, the maximum allowable pension cost) based on the actuarial accrued liability, normal cost, and unfunded actuarial liability. Under section 2142.4(A) of PRM–I, these liability measurements are to be computed in accordance with the Employee Retirement Income Security Act of 1974 (ERISA), regardless of whether or not the pension plan is subject to ERISA. Also, section 2142.6(A) of the PRM–I requires the current period liability for pension cost to be funded in order to be allowable. In addition, section 2142.6(C) of the PRM–I allows for funding in excess of the current period liability to be carried forward and recognized in future periods. We note that, on March 28, 2008, CMS published Revision 436, a technical clarification to section 2142 of the PRM–I.

Actuarial accrued liability and normal cost are typically determined on an ongoing plan basis using long-term, best-estimate assumptions. The interest assumption reflects the average rates of return expected over the period during which benefits were payable, taking into account the investment mix of plan assets. Pension costs for plans not subject to ERISA (such as church plans and plans sponsored by public sector employers) also are typically based on the actuarial accrued liability and normal cost using long-term, best estimate assumptions.

The Pension Protection Act (PPA) of 2006 (Pub. L. 109–280) amended ERISA. Under the PPA amendments to ERISA, the actuarial accrued liability and normal cost are no longer used as a basis for determining ERISA minimum required or maximum tax deductible contributions. ERISA contribution limits are now based on a "funding target" and "target normal cost" measured on a settlement basis using the current market interest rates for investment grade corporate bonds that match the duration of the benefit payouts. The Internal Revenue Service (IRS) publishes the applicable interest rate tables on a monthly basis. Because pension liabilities are very sensitive to changes in the interest rate used to discount future benefit payouts, pension costs based on the PPA "funding target" and "target normal cost" values are expected to be less stable than those based on the pre-PPA traditional long-term, best-estimate assumptions, which change infrequently. Furthermore, plans not subject to the ERISA requirements, as amended by the PPA, are not likely to use the new "funding target" and "target normal cost" basis for determining pension costs, and ERISA plans are not likely to continue to report costs developed using the actuarial accrued liability and normal cost based on long-term basis, best estimate assumptions. Accordingly, there is no longer a standard actuarial basis used by all plans.

In response to the PPA amendments to ERISA, we began a review of the rules for determining pension costs for Medicare cost-finding and wage index purposes. As an interim measure, we issued a Joint Signature Memorandum (JSM) in November 2009 that contained instructions and a spreadsheet to assist hospitals and Medicare contractors in determining the annual allowable defined benefit pension cost for the FY 2011 wage index (JSM/TDL–10061, 11–20–09, December 3, 2009). Although these instructions were released for purposes of the wage index, these instructions also serve as interim guidance for Medicare cost-finding purposes.

In this proposed rule, we are proposing to revise our policy for determining pension cost for Medicare purposes. As mentioned above, due to the ERISA rules, as amended by the PPA, there is no longer a standard actuarial cost basis to be used by all types of plans. Therefore, we are proposing to no longer rely on actuarial computation to determine the maximum annual cost limitation for Medicare. Instead, the general parameters of our proposal would maintain the current requirement that pension costs must be funded to be reportable, and would require all hospitals to report the actual pension contributions funded during the reporting period, on a cash basis.

In addition, under this cash basis approach, we are proposing separate methodologies for measuring pension costs for Medicare cost-finding purposes (discussed below under section IV.M.2. of this preamble) and for purposes of updating the wage index (discussed in section III.D.2. of this preamble). We believe it is necessary to have two distinct proposals in order to address the different goals of determining a hospital's payments and updating the average hourly wage to establish the geographic area wage index. The function of the wage index is to measure relative hospital labor costs across areas. This function is distinct from Medicare payment determinations, where the goal is to measure the actual costs incurred by individual hospitals. These two distinct proposals would require separate updated instructions to section 2142 of the PRM–I for Medicare cost-finding purposes and section 3605.2 of the PRM–II for purposes of the wage index. Below is a detailed discussion of our proposal of a new methodology for reporting pension costs for Medicare cost-finding purposes. A full discussion of our proposal for reporting pension costs under the wage index is discussed in section III.D.2. of this preamble.

The proposal below reflects our commitment to the general principles of the President's Executive Order released January 18, 2011, entitled "Improving Regulation and Regulatory Review."

2. Proposal for Allowable Defined Benefit Pension Plan Cost for Medicare Cost-Finding Purposes

As mentioned above, the defined benefit pension plan costs (hereafter referred to as "pension costs") reported for Medicare payment purposes should reflect the actual costs incurred by an individual provider. We are proposing to retain the policy in the current manual requiring pension costs to be funded in order to be reportable. We believe funding is an appropriate basis because it measures the actual expenditure towards the current period liability for pensions. We also are proposing to continue to limit the current period liability for pension costs

(that is, maximum annual allowable pension costs). However, we are proposing to change the methodology for calculating the limit on the current period liability. We are proposing that this methodology would be effective for cost reporting periods beginning on or after October 1, 2011.

Specifically, we are proposing a limit on the current period liability equal to 150 percent of the three consecutive reporting periods out of the recent reporting which produce the highest average. We believe a threshold of 150 percent is appropriate for the following reasons: First, the proposed threshold should be adequate to allow for typical fluctuations in contributions and for inflation. Second, we believe a threshold is necessary to limit the current period liability in order to ensure that reported pension costs are reasonable and do not reflect excessive or advance funding in any particular year. In addition, the proposed limit would help ensure that pension costs in the current year are reasonable because we expect the limit to capture pension costs which relate exclusively to patient care services furnished in the current cost reporting period. While we are proposing a limit, we recognize there may be situations in which pension costs in excess of the 150-percent limit might be reasonable, such as a funding requirement imposed by a third party, that is, ERISA's minimum funding requirement, statute or collective bargaining agreement. Therefore, we are proposing a process to allow hospitals with contributions in excess of the proposed limit to submit documentation demonstrating that all or a portion of the "excess" costs are reasonable and necessary for a particular cost reporting period.

The proposed 150-percent limit was established based on an analysis of historical contribution data submitted by pension plans subject to ERISA and published by the U.S. Department of Labor (DOL). Based on our analysis of the DOL contribution data, we expect the limit to apply only in a small minority of cases. We believe the use of readily available historical contribution data to establish the limitation will avoid the complexity of a limitation based on technical actuarial measurements. A limit based on the three consecutive reporting periods out of the five most recent reporting periods which produce the highest average will help to ensure that periods when no contributions (or only minimal contributions) are made will not dramatically reduce the limit in subsequent periods.

We believe use of a 5-year period would minimize the administrative burden on providers that would be associated with a longer period. We also believe using the three consecutive reporting periods which produce the highest average will better reflect a typical average pension cost while use of contributions for any three periods, even nonconsecutive, could introduce atypical results. Specifically, using the three highest contributions in the 5-year period may overstate the average contribution. However, because excessive contributions tend to reduce future funding requirements, we believe it would be unusual for excessive contributions to occur in three consecutive periods.

While we are proposing a limit, we believe that providers' pension costs in excess of the 150-percent limit that are not considered reasonable for the current cost reporting period under the proposed review process are likely to be prefunded pension costs attributable to the patient care services for a future cost reporting period. Therefore, similar to the current instruction in section 2142.6(C) of the PRM–I, we are proposing to continue to use a carry forward policy. Specifically, we are proposing that current period contributions in excess of the 150-percent limit that are not considered reasonable for the current cost reporting period under the proposed review process be carried forward and reported in future period(s) as the applicable limit for the future period(s) will allow. Medicare contractors would be required to maintain historical data in order to determine the 150-percent limit and track any carry forward amounts. We anticipate making a worksheet available for this purpose.

We are interested in public comments as to documentation or criteria that would be appropriate for the review process proposed above. We also invite public comments on this proposal and are especially interested in receiving public comments related to our proposal to limit the reportable pension amount.

N. Rural Community Hospital Demonstration Program

1. Background

Section 410A(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing "rural community hospitals" to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration program pays rural community hospitals for such services under a cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1) of MMA, is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A(a)(4) of Public Law 108–173, in conjunction with paragraphs (2) and (3) of section 410A(a), provided that the Secretary was to select for participation no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S. Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration program: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming. (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003.)

We originally solicited applicants for the demonstration program in May 2004; 13 hospitals began participation with cost reporting years beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the program and became CAHs. In a notice published in the **Federal Register** on February 6, 2008 (73 FR 6971), we announced a solicitation for up to 6 additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These four additional hospitals began under the demonstration program payment methodology with the hospital's first cost reporting period starting on or after July 1, 2008. At that time, there were 13 hospitals participating in the demonstration program.

Five hospitals (3 of the hospitals were among the 13 hospitals that were original participants in the demonstration program and 2 of the hospitals were among the 4 hospitals that began the demonstration program in 2008) withdrew from the

demonstration program during CYs 2009 and 2010. (Three of these hospitals indicated that they would be paid more for Medicare inpatient services under the rebasing option allowed under the SCH methodology provided for under section 122 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). One hospital restructured to become a CAH, and one hospital closed.) These actions left 8 hospitals participating in the demonstration program as of November 1, 2010.

In addition, section 410A(c)(2) of Public Law 108–173 required that, "[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented." This requirement is commonly referred to as "budget neutrality." Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral in its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration program could be viable under the usual form of budget neutrality. Specifically, cost-based payments to participating small rural hospitals are likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration program is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these same hospitals.

In the past seven IPPS final regulations, spanning the period for which the demonstration program has been implemented, we have adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. As we discussed in the FY 2005, FY 2006, FY 2007, FY 2008, FY 2009, FY 2010, FY 2011 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, and 75 FR 50343 respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner. In light of the statute's budget neutrality requirement, we are proposing a methodology to calculate a budget neutrality adjustment factor to the FY 2012 national IPPS rates.

2. Changes to the Demonstration Program Made by the Affordable Care Act

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) amended section 410A of Public Law 108–173, which established the rural community hospital demonstration program. Sections 3123 and 10313 of the Affordable Care Act changed the rural community hospital demonstration program in several ways. First, the Secretary is required to conduct the demonstration program for an additional 5-year period that begins on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173, as amended (section 410A(g)(1) of Public Law 108–173, as added by section 3123(a) of the Affordable Care Act and further amended by section 10313 of that Act). Further, the Affordable Care Act requires that, in the case of a rural community hospital that is participating in the demonstration program as of the last day of the initial 5-year period, the Secretary shall provide for the continued participation of such rural hospital in the demonstration program during the 5-year extension, unless the hospital makes an election, in such form and manner as the Secretary may specify, to discontinue participation (section 410A(g)(4)(A) of Pub. L. 108–173, as added by section 3123(a) of the Affordable Care Act and further amended by section 10313 of such Act). In addition, the Affordable Care Act provides that during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary to 20 (section 410A(g)(2) of Pub. L. 108–173, as added by section 3123(a) and amended by section 10313 of the Affordable Care Act). Further, the Secretary is required to use the same criteria and data that the Secretary used to determine the States under section 410A(a)(2) of Public Law 108–173 for purposes of the initial 5-year period. The Affordable Care Act also allows not more than 30 rural community hospitals in such States to participate in the demonstration program during the 5-year extension period (section 410A(g)(3) of Public Law 108–173, as added by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of such Act). Additionally, we note that we indicated in the FY 2011 IPPS final rule (75 FR 50343) that section 410A(g)(4)(b) of Public Law 108–173 as added by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of that Act provides that the amount of payment under the demonstration program for covered inpatient hospital services furnished in a rural community hospital [other than services furnished in a psychiatric or rehabilitation unit of the hospital that is a distinct part] is the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period. We want to clarify that we believe that section 410A(g)(4)(B) of Public Law 108–173, as added by section 3123(a) the Affordable Care Act and as further amended by section 10313 of such Act, provides this with respect to a rural community hospital that is participating in the demonstration program under section 410A as of the last day of the initial 5-year period. Specifically, the Affordable Care Act requires that in the case of a rural community hospital that is participating in the demonstration as of the last day of the initial 5-year period, the Secretary in calculating payments under subsection (b) shall substitute under paragraph (1)(A) the phrase "the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period" for the phrase "the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration." The phrase "the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration" does not precisely track the language in section 410A(b)(1)(A) of

Public Law 108–173, therefore we cannot delete and replace as described in the Affordable Care Act. However, we believe the language of section 410A(g)(4)(B)(i) of Public Law 108–173 as amended is clear. Namely, a rural community hospital that is participating in the demonstration as of the last day of the initial 5-year period shall be paid for its covered inpatient hospital services "the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period." (This methodology does not apply to services furnished in a psychiatric or rehabilitation unit of the hospital which is a distinct part.) For discharges occurring in a subsequent cost reporting period during the demonstration, the formula in section 410A(b)(1)(B) of Public Law 108–173, as amended, would apply to such hospitals. That is, the payment will be the lesser of reasonable cost or the target amount. We calculate the target amount in the second cost reporting period by taking the reasonable costs of providing covered inpatient hospital services in the first cost reporting period beginning on or after the first day of the 5-year extension and increasing it by the IPPS market basket percentage increase for that particular cost reporting period. We calculate the target amount in subsequent cost reporting periods by taking the preceding cost reporting period's target amount and increasing it by the IPPS market basket percentage increase for that particular cost reporting period. (We note that in calculating target amounts we utilize the IPPS market basket percentage increase as defined in section 1886(b)(3)(B)(iii), opposed to the applicable percentage increase as defined in section 1886(b)(3)(B)(i) of the Act. We note that section 410A(b)(2)(B) of Public Law 108–173, in pertinent part, provides that target amounts are "increased by the applicable percentage increase (under clause (i) of section 1886(b)(3)(B) of the Social Security Act * * *) in the market basket percentage increase (as defined in clause (iii) of such section) for that particular cost reporting period." The phrase "applicable percentage increase (under clause (i) of section 1886(b)(3)(B) of the Social Security Act * * *) in the market basket percentage increase * * *" is ambiguous as there is no applicable percentage increase in the market basket percentage increase. Because the focus of the provision is the amount of the IPPS market basket percentage increase, we believe the provision is addressing the IPPS market basket percentage increase, and not the applicable percentage increase, which includes other adjustments to the market basket percentage increase. Further, because section 410A(b)(2)(B) of Public Law 108–173 is addressing target amounts under the demonstration we believed it was logical to read the statute as providing for an update structure mimicking the update structure for target amounts of reasonable cost-based providers like children's and cancer hospitals, as well as RNCHIs. This rationale applies any time we use the IPPS market basket percentage increase to update target amounts in the demonstration. With respect to hospitals that are newly joining the demonstration, they are paid the reasonable costs of providing covered inpatient hospital services, other than services furnished in a psychiatric or rehabilitation unit of the hospital which is a distinct part, for discharges occurring in the hospital's first cost reporting period beginning on or after the implementation of the demonstration program (section 410A(b)(1)(A) of Pub. L. 108–173). We have determined that each of these new hospitals will begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011. We chose this date because it follows immediately upon the notification of the hospitals of their acceptance to the demonstration and it will allow the hospitals to begin participation in the demonstration as soon as possible. With respect to rural community hospitals newly joining the demonstration, for discharges occurring in a subsequent cost reporting period under the demonstration program, the formula in section 410A(b)(1)(B) of Public Law 108–173, as amended, would apply. That is, payments will be the lesser amount of reasonable costs or the target amount. We calculate the target amount in the second cost reporting period by taking the reasonable costs of providing covered inpatient hospital services in the first cost reporting period and increasing it by the IPPS market basket percentage increase for that particular cost reporting period. We calculate the target amount in subsequent cost reporting periods by taking the preceding cost reporting period's target amount and increasing it by the IPPS market basket percentage increase for that particular cost reporting period. In addition, various other technical and conforming changes were made to section 410A of Public Law 108–173 by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of that Act.

We published a solicitation for applications for additional participants in the Rural Community Hospital Demonstration Program in the **Federal Register** on August 30, 2010 (75 FR 52960). Applications were due on October 14, 2010. The 20 States with the lowest population density, which are eligible for the demonstration program are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). We approved 19 new hospitals for participation in the demonstration program. As of this date, we are waiting for these hospitals to respond as to whether they accept the terms and conditions stipulated for their participation in the demonstration; therefore, it is possible that fewer than the total of 19 will participate. We have based cost estimates for the demonstration for this new set of hospitals based on the assumption that all 19 hospitals will elect to participate. If fewer actually make this election, we are proposing to accordingly adjust the demonstration cost estimates in the FY 2012 IPPS/LTCH PPS final rule.

3. Proposed FY 2012 Budget Neutrality Adjustment

In order to ensure that the demonstration is budget neutral as is required by the statute, we are proposing to adjust the national IPPS rates in this proposed rule to account for any added costs attributable to the demonstration program. Specifically, the proposed budget neutrality adjustment would account for: (1) The estimated costs of the demonstration program in FY 2012 for the 8 currently participating hospitals ("pre-expansion participating hospitals"); (2) the estimated costs of the demonstration in FY 2012 for the 19 hospitals newly selected to begin participation in the demonstration program; and (3) the amount by which the costs of the demonstration program, as indicated by settled cost reports for cost reporting periods beginning in FYs 2007 and 2008 for hospitals participating in the demonstration program during FYs 2007 and 2008, exceeded the amount that was identified in the FY 2007 and FY 2008 IPPS final rules as the budget neutrality offsets for FYs 2007 and 2008.

a. Component of the Proposed FY 2012 Budget Neutrality Adjustment That Accounts for Estimated FY 2012 Demonstration Program Costs of the "Pre-Expansion Participating Hospitals"

We note that eight hospitals that were selected for participation in either 2005 or 2008 are currently continuing to participate in the extension period mandated by the Affordable Care Act. We are proposing that the component of the proposed FY 2012 budget neutrality adjustment to the national IPPS rates that accounts for the estimated demonstration program costs in FY 2012 for the eight "pre-expansion participating hospitals" would be calculated by utilizing three separate methodologies: one methodology for the six hospitals that have participated in the demonstration program since its inception and that are continuing to participate in the demonstration program ("originally participating hospitals"); a second methodology for one hospital that is currently participating in the demonstration program and that was among the four hospitals that joined the demonstration program in 2008; and a third methodology for the other hospital that is currently participating in the demonstration program and that was among the four hospitals that joined the demonstration program in 2008. Different methods are used for these three sets of hospitals because the data available to us to estimate the demonstration program costs for each is different. Specifically, we are proposing to use the following hospital cost reports as the data sources used to estimate the costs attributable to the demonstration program under section 410A of Pub. L. 108–173 as amended:

(1) For the six "originally participating hospitals", the estimate of the portion of the proposed budget neutrality adjustment that accounts for the estimated FY 2012 demonstration program costs is based on data from their settled cost reports applicable to the second year of the demonstration—that is, for cost reporting periods ending in FY 2007. We are proposing to use these cost reports because they are the most recent finalized cost reports and, thus, we believe their accounting of costs is the most accurate indicator available to us at this time to estimate FY 2012 demonstration costs.

(2) For one of the two hospitals that joined the demonstration program in 2008, and that are still participating, we are proposing to estimate the FY 2012 demonstration program costs under section 410A of Public Law 108–173 as amended based on data from its as submitted cost report beginning January 1, 2008. Because we do not have final settled cost reports for this hospital for either 2008 or 2009, we are proposing to rely on its "as submitted" cost report for this period to estimate FY 2008 demonstration program costs for that hospital. We are proposing to use the "as submitted cost report" because we believe that as it is among the most recent cost reports, its accounting of costs is the most accurate indicator available to us at this time to estimate costs under the demonstration.

(3) The remaining hospital of the eight "pre-expansion participating hospitals", which began participation in FY 2008, is an Indian Health Service provider. Historically, the hospital has not filed standard Medicare cost reports. To estimate its costs for FY 2012, we are proposing to use its full "as submitted" cost report filed for the period ending September 30, 2009. We are proposing to use this "as submitted" cost report because as among the most recent cost reports we believe it allows us to estimate FY 2012 costs accurately.

We are proposing to use the same general methodology as for the FY 2011 IPPS/LTCH PPS final rule, but providing more detail. The proposed methodology for calculating the estimated FY 2012 demonstration cost for the eight "pre-expansion hospitals" is as follows:

Step 1: In order to calculate demonstration costs for each of the six "originally participating hospitals" for the cost reporting period ending in FY 2007, we subtracted the amount it would have otherwise been paid under the applicable payment system(s) for covered inpatient hospital services without the demonstration during such period (as indicated on the settled cost report for this period) from the amount paid to it for such services under the reasonable cost methodology in section 410A(b) of Public Law 108–173 (as indicated on the settled cost report for this period). Steps 1(a) through (c) below are performed to calculate FY 2007 demonstration costs for these six hospitals. (We are proposing to use final settled cost reports ending in FY 2007 to represent FY 2007 demonstration costs for each of these hospitals because a substantial portion of the months included within these cost report years (respective to each hospital) fall within FY 2007, and, therefore we believe that for purposes of this analysis it is appropriate to consider data from these cost reports to represent FY 2007 inpatient costs for the demonstration during that period. In addition, we note that throughout the remainder of the preamble discussion on the budget neutrality adjustment for the rural community hospital demonstration we refer to "covered inpatient hospital services" as that term is defined in section 410A(f)(2) of Public Law 108–173 as amended as "inpatient hospital services." We also note that the phrase "the reasonable cost methodology" means the reasonable cost methodology in section 410A(b) of Public Law 108–173 or the reasonable cost methodology in section 410A(b) of Public Law 108–173, as amended as applicable in the particular situation.

- Step 1(a): First, for each hospital, we subtracted the amount that would otherwise be paid under the IPPS for the hospital's inpatient hospital services (excluding those associated with swing beds) for the cost reporting period ending in FY 2007 (as indicated on the settled cost report for this period) from the amount paid for such services under the reasonable cost methodology (as indicated on the settled cost report for this period). The result of this difference is each hospital's demonstration costs for its inpatient hospital services (excluding those associated with swing beds) for the cost reporting period ending in FY 2007. (We used the amount the hospital would otherwise be paid under the IPPS as indicated above because this is the payment methodology under which the hospital's beds (excluding swing beds) would be paid in the absence of the demonstration. This rationale applies throughout the preamble discussion on the rural community hospital demonstration budget neutrality adjustment whenever this is a component of the proposed methodology.)
- Step 1(b): Next, with respect to the hospitals that have swing beds, we subtracted the amount the hospital would otherwise be paid under section 1888(e)(7) of the Act for the inpatient hospital services associated with the swing beds for the cost reporting period ending in FY 2007 (as indicated in the settled cost report for this period) from the amount paid for such services under the reasonable cost methodology (as indicated in the settled cost report for such period). The result of this difference is each hospital's demonstration costs associated with its swing beds for the cost reporting period ending in FY 2007. (We used the amount the hospital would otherwise be paid under section 1888(e)(7) of the Act as indicated above because this is the payment methodology under which the hospital's swing beds would be paid in the absence of the demonstration. This rationale applies throughout the preamble discussion on the rural

community hospital demonstration budget neutrality adjustment whenever this is a component of the proposed methodology.)

• Step 1(c): Next, in order to calculate total estimated FY 2010 demonstration costs for all six hospitals, we added together the differences calculated above in Step 1(a) and Step 1(b) as applicable for each of the six hospitals and then multiplied this sum by the IPPS market basket percentage increases for FYs 2008 through 2010, which were adopted in the respective IPPS final rules and a 2-percent annual volume adjustment for the years 2008 through 2010.

We note that we are proposing to apply the applicable IPPS market basket percentage increases described above to model estimated FY 2010 demonstration costs because we believe that this update factor appropriately indicates the trend of increase in hospital operating costs. Further, this approach is consistent with the agency's use of the IPPS market basket percentage increase to update the rate-of-increase limits (which is a reasonable cost-based methodology) for children's and cancer hospitals as well as RNCHIs. Therefore, we believe it enables us to estimate appropriately demonstration costs that are tied to a reasonable cost-based methodology. Also, this approach is consistent with how we update target amounts under the demonstration under section 410A(b)(2)(B) of Public Law 108–173. The proposed 2-percent annual volume adjustment was stipulated by the CMS Office of the Actuary in 2004, at the outset of the demonstration and is supposed to accurately reflect the tendency of hospitals' volumes to increase. We acknowledge the possibility that volumes for small hospitals may fluctuate, and are incorporating into the estimate of demonstration costs a factor to allow for a potential increase. We note that the rationale provided herein for utilizing an IPPS market basket percentage increase and a 2-percent annual volume adjustment to estimate demonstration costs is applicable throughout the preamble discussion on the rural community hospital budget neutrality adjustment whenever these factors are used in the proposed methodology.

As a side note, as a special feature of the demonstration, we added a supplemental work sheet to the standard hospital cost report which is completed by the fiscal intermediary in the final settlement for these six "originally participating hospitals." This supplemental work sheet includes the calculation of the hospital's first year reasonable costs of inpatient hospital services (excluding those associated with swing beds) as set forth in section 410A of Public Law 108–173, and, in addition, for the hospital's second year cost reports (those cost reports ending in FY 2007), the target amount (that is, the previous year's Medicare reasonable cost amount for inpatient hospital services updated by the IPPS market basket percentage increase as provided in section 410A(b)(2)(B) of Pub. L. 108–173). This supplemental work sheet also includes a calculation of the amount that would otherwise be paid for the hospital's inpatient hospital services under the IPPS, as is ordinarily presented on the standard hospital cost report. For hospitals that have swing beds, this supplemental work sheet also includes the following: the estimated amount the hospital would otherwise be paid under section 1888(e)(7) of the Act for the inpatient hospital services associated with the hospital's swing beds; the estimated amount the hospital would be paid under the reasonable cost methodology for the inpatient hospital services provided in its swing beds, and the hospital's target amount for its swing beds.

Step 2: In order to calculate estimated FY 2008 demonstration costs for the non-Indian Health Service hospital that began the demonstration program in 2008, we subtracted the estimated amount it would have otherwise been paid for inpatient hospital services without the demonstration under the applicable payment system(s) (as indicated on the "as submitted" cost report beginning January 1, 2008) from the estimated costs of such services under the reasonable cost methodology (as indicated on the "as submitted" cost report for this period). Steps 2(a) through (c) below are performed to calculate this amount. We note that we are proposing to use the cost report beginning January 1, 2008 to represent FY 2008 demonstration costs for this hospital because it corresponds most precisely to FY 2008 and, therefore, we believe correctly represents FY 2008 inpatient costs for the demonstration for that period.

• Step 2(a): Specifically, we subtracted the estimated amount that would otherwise be paid under the IPPS for the hospital's inpatient hospital services (excluding swing beds) for the cost reporting period beginning January 1, 2008 (as indicated on the "as submitted" cost report) from the estimated amount to be paid for such services under the reasonable cost methodology (as indicated on the "as submitted" cost report for such period).

• Step 2(b): Next, we subtracted the estimated amount that would otherwise be paid under section 1888(e)(7) of the Act for the inpatient hospital services associated with the swing beds during the cost reporting period beginning January 1, 2008 (as indicated on the "as submitted" cost report) from the estimated amount to be paid for such services under the reasonable cost methodology as indicated on the "as submitted" cost report for such period.

• Step 2(c): We added together the differences calculated in Steps 2(a) and (b) above to obtain the hospital's total estimated FY 2008 demonstration cost.

• Step 2(d): Then, in order to calculate the hospital's estimated FY 2010 demonstration costs, we took the amount calculated in Step 2(c) above and multiplied it by the IPPS market basket percentage increases for FYs 2009 and 2010 as adopted in the respective IPPS final rules and a 2-percent annual volume adjustment for each of FYs 2009 and 2010.

Step 3: In order to calculate the estimated FY 2009 demonstration costs for the Indian Health Service provider, we subtracted the estimated amount the hospital would have otherwise been paid for inpatient hospital services without the demonstration under the applicable payment system (as indicated on the "as submitted" cost report ending September 30, 2009) from the estimated costs for such services under the reasonable cost methodology (as indicated in the "as submitted" cost report for such period). Step 3(a) below is performed to calculate this amount. (We note that we are proposing to use the cost report ending September 30, 2009 to represent FY 2009 demonstration costs for this hospital because it corresponds most precisely to FY 2009 and, therefore, we believe correctly represents FY 2009 inpatient costs for the demonstration for that period.)

• Step 3(a): Specifically, we subtracted the estimated amount the hospital would have otherwise been paid for inpatient hospital services under the IPPS in the cost reporting period ending September 30, 2009 without the demonstration (as indicated on the "as submitted" cost report for this period) from the estimated amount to be paid under the reasonable cost methodology for such services (as indicated in the "as submitted" cost report for such period). We note that this provider had no swing beds, therefore, we did not estimate any portion of the costs under section 1888(e)(7) of the Act.

• Step 3(b): Next, in order to calculate the Indian Health Service provider's

estimated FY 2010 demonstration costs, we multiplied the difference calculated in Step 3(a) above by the IPPS market basket percentage increase for FY 2010 adopted in the FY 2010 IPPS/LTCH PPS final rule and the 2-percent annual volume adjustment.

Step 4: Then, in order to calculate total estimated FY 2010 demonstration costs for all eight "pre-expansion participating hospitals", we added the estimated FY 2010 demonstration costs calculated in Steps 1(c), 2(d), and 3(b) above.

Step 5: Next, in order to calculate total estimated FY 2012 demonstration costs for all eight "pre-expansion hospitals", we multiplied the amount calculated in Step 4 above by the FY 2011 IPPS market basket percentage increase adopted in the FY 2011 IPPS/LTCH PPS final rule and the proposed FY 2012 IPPS market basket percentage increase contained elsewhere in this proposed rule and a 2-percent annual volume adjustment for FYs 2011 and 2012. Thus, we arrived at the total estimated FY 2012 demonstration costs for all eight currently participating hospitals which needs to be offset, which is $21,290,305. If updated data become available for the final rule, we are proposing to use them to estimate the costs of the demonstration program in FY 2012 (including the use of any change in the FY 2012 market basket percentage increase).

b. Portion of the Proposed FY 2012 Budget Neutrality Adjustment That Accounts for Estimated FY 2012 Demonstration Program Costs for Hospitals Newly Selected To Participate in the Demonstration Program

Section 410A(g)(3) of Public Law 108–173, as added by section 3123 of the Affordable Care Act and as further amended by section 10313 of such Act, provides that "[n]otwithstanding subsection (a)(4), during the 5-year extension period, not more than 30 rural community hospitals may participate in the demonstration program under this section." Consequently, up to 22 additional hospitals may be added to the demonstration program (30 hospitals minus the 8 "pre-expansion participating hospitals"). In order to ensure budget neutrality for the 19 newly selected hospitals, we are proposing to include a component in the proposed budget neutrality adjustment factor to the proposed FY 2012 national IPPS rates to account for the estimated FY 2012 costs of those new hospitals. For this proposed rule, we are proposing to generally use "as submitted" cost reports to estimate demonstration costs because they are the most recent cost reports and, therefore, we believe most accurately reflect the hospital's cost and payment for Medicare inpatient services in the respective year. We note that hospitals were required to submit pages from their most recent cost reports with their applications. For 13 of these hospitals, these cost reports had end dates in FY 2009; for the 6 remaining hospitals, they had end dates in FY 2010. Therefore, in various steps in the proposed methodology below, we begin various estimates with FY 2009 if the hospital submitted a cost report ending in FY 2009, and FY 2010 if the hospital submitted a cost report ending in FY 2010.

We are proposing to use the following methodology in order to estimate FY 2012 demonstration program costs for the 19 newly selected hospitals. This methodology differs from that in the FY 2011 IPPS/LTCH PPS final rule, because, at that time, hospitals had not been selected for participation, and thus we had no data specific to those hospitals that would enter the demonstration as a result of its expansion mandated by the Affordable Care Act.

Step 1(a): For each hospital that submitted a cost report ending in FY 2009, we subtracted the estimated amount that would be paid for its inpatient hospital services (excluding those associated with swing beds) under the IPPS for such period (as indicated on the "as submitted" cost report for such period) from the estimated amount for reasonable costs for such services (as indicated on the "as submitted" cost report for such period) in order to calculate the difference between the hospital's estimated cost and payment for its inpatient hospital services (excluding those associated with swing beds) during the cost reporting period ending in FY 2009.

Step 1(b): For each hospital that submitted a cost report ending in FY 2010, we subtracted the estimated amount that would be paid for its inpatient hospital services (excluding those associated with swing beds) under the IPPS (as indicated on the "as submitted" cost report for such period) from the estimated amount for the reasonable cost for such services (as indicated on the "as submitted" cost report for such period) in order to calculate the difference between the hospital's estimated costs and payment for its inpatient hospital services (excluding those associated with swing beds) during such period.

Step 1(c): While a portion of the 19 newly selected hospitals that have swing beds reported estimated costs for those beds, some hospitals did not, namely a portion of the hospitals that submitted cost reports ending in FY 2009 with their applications. Therefore, we needed to gap-fill in order to account for this issue. For each of the hospitals with swing beds that submitted cost reports ending in FY 2009, but that did not submit with its application estimated costs associated with those swing beds, we assigned an estimated cost for its swing beds based on an average of the estimated cost-payment difference associated with the swing beds of the newly participating hospitals that reported such data on their applications. We are proposing to assign estimated costs based on the average of the cost-payment difference for those hospitals that submitted these data, because these hospitals represent a sample of hospitals chosen for the demonstration, which we believe can accurately reflect costs and payment. We believe that these amounts, derived from the applications of the hospitals that submitted these data, accurately reflect this sample because they are hospitals of similar size and circumstances. Furthermore, these hospitals, which submitted the data, were chosen from the same set of States as the overall set of the newly selected hospitals. We utilized the methodology in Steps 1(c)(i) through (c)(iii) below to calculate this amount:

- Step 1(c)(i): For each of the hospitals with swing beds that submitted with its application both a cost report ending in FY 2009 and estimated costs of those swing beds during such period, we calculated its estimated cost-payment difference between the amount that the hospital estimates that will be paid under section 1888(e)(7) of the Act during such period for those swing beds (that is, the amount that the hospital estimates that will be paid under section 1886(e)(7) for the inpatient hospital services associated with its swing beds for such period from the amount that the hospital estimates that it would be paid for the reasonable costs for such services during such period as those amounts are reported on the hospital's application) by simply taking this amount from the hospital's application.
- Step 1(c)(ii): Then, for each of the hospitals with swing beds that submitted with its application both a cost report ending in FY 2010 and the estimated costs of those swing beds during such period, we calculated the difference between the estimate costs and payment for those swing beds for such period by simply taking this amount from the hospital's application. (We note that all hospitals that had

swing beds and that submitted cost reports ending in FY 2010 with their application supplied data on the estimated cost and payment for swing bed services on these cost reports.)

- Step 1(c)(iii): Next, we totaled all of the individual amounts calculated under Steps 1(c)(i) and (c)(ii) above and then divided this amount by the total number of hospitals that provided data on estimated costs on swing beds in their applications. We used the result of this computation as the estimated cost for the swing beds for each of the hospitals that failed to submit estimated costs for those beds with their applications.
- *Step 1(d):* Then, in order to calculate the total costs during the cost reporting period ending in FY 2009 for each hospital that submitted a cost report ending in FY 2009, we did the following: (a) If the hospital had no swing beds, its total estimated costs for such period is the difference calculated under Step 1(a); (b) If the hospital had swing beds, we added the difference calculated under Step 1(a) with the difference calculated under Step 1(c)(i) or Step 1(c)(iii) as applicable.
- *Step 1(e):* Next, in order to calculate total estimated FY 2009 costs for all of the hospitals that submitted cost reports ending in FY 2009 with their applications, we added together all of the total estimated costs that were calculated for each such hospital under Step 1(d) above. We note that we believe that using cost reports ending in FYs 2009 and 2010 best reflect costs and payment in FYs 2009 and 2010 because these cost reports most closely respond to those fiscal years.
- *Step 1(f):* Then, in order to calculate the total estimated FY 2011 costs for the newly selected hospitals that submitted cost reports ending in FY 2009 with their applications, we multiplied the amount calculated in Step 1(e) above by the FYs 2010 and 2011 IPPS market basket percentage increases adopted in the respective IPPS/LTCH PPS final rules as well as a 2-percent annual volume adjustment for each of FYs 2010 and 2011.
- *Step 1(g):* Then, in order to calculate the total estimated FY 2010 costs for each hospital that submitted a cost report ending in FY 2010, we did the following: (a) If the hospital had no swing beds, its total estimated costs is the difference calculated under Step 1(b); (b) If the hospital had swing beds, we added the difference calculated under Step 1(b) with the difference calculated under Step 1(c)(ii).
- *Step 1(h):* Next, in order to calculate the total FY 2010 costs for all of the hospitals that submitted FY 2010 cost reports with their applications, we added together all of the total estimated FY 2010 costs calculated for each such hospital under Step 1(g) above.
- *Step 1(i):* Then, we calculated the total estimated FY 2011 costs for all of the newly selected hospitals that submitted cost reports ending in FY 2010 by multiplying the amount calculated in Step 1(h) above by the FY 2011 IPPS market basket percentage increase adopted in the respective IPPS/LTCH PPS final rule as well as a 2-percent annual volume adjustment for FY 2011.
- *Step 1(j):* Next, in order to calculate total estimated FY 2012 demonstration costs for all of the 19 newly selected hospitals, we added together the amounts calculated in Steps 1(f) and 1(i) above and then multiplied this sum by the proposed IPPS FY 2012 market basket percentage increase proposed elsewhere in this proposed rule and a 2-percent annual volume adjustment for FY 2012. The amount of the estimated FY 2012 demonstration costs for the 19 newly selected hospitals needing to be offset is $31,351,908. If updated data become available for the final rule, we are proposing to use them to estimate the costs of the demonstration program in FY 2012.

c. Portion of the Proposed FY 2012 Budget Neutrality Adjustment To Offset the Amount by Which the Costs of the Demonstration Program in FYs 2007 and 2008 Exceeded the Amount That Was Identified in the FYs 2007 and 2008 IPPS Final Rules as the Budget Neutrality Offset for FYs 2007 and 2008

In addition, in order to ensure that the demonstration program in FYs 2007 and 2008 was budget neutral, we are proposing to incorporate a component into the budget neutrality adjustment factor to the proposed FY 2012 national IPPS rates, which would offset the amount by which the demonstration program costs as indicated by settled cost reports beginning in FYs 2007 and 2008 for hospitals participating in the demonstration program during FYs 2007 and 2008 exceeded the amount that was identified in the FYs 2007 and 2008 IPPS final rules as the budget neutrality offset for FYs 2007 and 2008. Specifically, we are proposing the following methodology. This is the same methodology as used in the FY 2011 IPPS/LTCH PPS final rule, but we are adding detail. In this proposed rule, we are recognizing the possibility that in the year's time between the FY 2011 and FY 2012 final rule that the cost reports for the cost reporting years beginning in FY 2008 for the hospitals then participating in the demonstration may be finalized, that is, settled.

- Step One: Calculate the costs of the demonstration program for each of FYs 2007 and 2008 according to the settled cost reports that began in FYs 2007 or 2008 for the then participating hospitals (which represent the third and fourth years of the demonstration program for each of the then participating hospitals) and then add these two sums together. The costs of the demonstration program for each of FYs 2007 and 2008 is the difference resulting from subtracting the total amount that would otherwise be paid to the then participating hospitals under the applicable payment system(s) (that is, under the IPPS and under section 1888(e)(7) of the Act to the extent the participating hospital had swing beds) without the demonstration from the amount paid to those hospitals under the demonstration payment methodology in section 410A(b) of Public Law 108–173. (We are proposing to use these settled cost reports, which represent the third and fourth years of the demonstration program for each of the then participating hospitals, and, therefore, we believe correctly represent inpatient costs for the demonstration program during each of those 2 years.) These settled cost reports represent the third and fourth years of the demonstration, because the demonstration started with cost report start dates on or after October 1, 2004. Therefore, the first year of the demonstration program is represented by cost reports with a start date between October 1, 2004 and September 30, 2005 (that is, FY 2005; the second year of the demonstration program is represented by cost reports with a start date between October 1, 2005 and September 30, 2006 (FY 2006); the third year of the demonstration program is represented by cost reports with a start date between October 1, 2006 and September 30, 2007 (FY 2007); and the fourth year of the demonstration program is represented by cost reports with a start date between October 1, 2007 and September 30, 2008 (FY 2008).
- Step Two: Subtract the amount that was offset by the budget neutrality adjustment for FYs 2007 and 2008 ($9,197,870 for FY 2007 and $9,681,893 for FY 2008) from the combined costs of the demonstration program in FYs 2007 and 2008 as calculated in Step one.
- Step Three: The result of Step two is a dollar amount, for which we would calculate a factor that would offset such amounts and would be incorporated into the overall proposed budget neutrality adjustment to the proposed national IPPS rates for FY 2012. This specific component to the overall

proposed budget neutrality adjustment for FY 2012 would account for the difference between the combined costs of the demonstration program in FYs 2007 and 2008 and the amount of the budget neutrality adjustment published in the FYs 2007 and 2008 IPPS/LTCH PPS final rules and, therefore, would ensure that the demonstration program is budget neutral for FYs 2007 and 2008.

Because of delays in the settlement process for the demonstration hospitals' third and fourth year cost reports, that is, for cost reporting periods starting in each FYs 2007 and 2008 respectively, we are unable to state the costs of the demonstration program corresponding to FYs 2007 and 2008 for purposes of determining the amount by which the costs corresponding to FYs 2007 and 2008 exceeded the amount offset by the budget neutrality adjustment for FYs 2007 and 2008. Therefore, we are not proposing the specific numeric amount representing this offsetting process that would be incorporated into the budget neutrality adjustment applied to the national IPPS rates. We note that we anticipate that they may be available for the FY 2012 IPPS/LTCH PPS final rule. Therefore, the estimated adjustment to the national IPPS rates in this proposed rule cannot include a component to account for these costs. However, to the extent such data is available for the final rule, we are proposing to have the budget neutrality offset to the IPPS rates account for the amount by which the costs corresponding to FYs 2007 and 2008 exceeded the amount offset by the budget neutrality adjustments for FYs 2007 and 2008 as calculated by the process described above.

For this FY 2012 IPPS/LTCH PPS proposed rule, the estimated amount for which an adjustment to the proposed national IPPS rates is being calculated is the sum of the amounts specified in sections IV.N.3.a. and IV. N.3.b. of this proposed rule, which is $52,642,213 (this estimate does not account for the numeric result of the method in IV.N.3.c.). As explained previously, to the extent the numeric result of the method in IV.N.3.c. is available in the final rule, under our proposal, this amount would be included in the amount which needs to be offset by the budget neutrality adjustment. Sections IV.N.3.a. and IV.N.3.b. of this proposed rule state dollar amounts, which represent estimated costs attributable to the demonstration program for the respective component of the overall estimated calculation of the proposed budget neutrality factor for FY 2012. This estimated amount is based on the specific assumptions identified, as well as from data sources that are used because they represent either the most recently finalized, (that is, settled) or, if "as submitted," recently available cost reports.

O. Bundling of Payments for Services Provided to Outpatients Who Later Are Admitted as Inpatients: 3-Day Payment Window

1. Background

Section 1886(a)(4) of the Act includes in the definition of "operating costs of inpatient hospital services" diagnostic services (including clinical diagnostic laboratory tests) or other services related to the admission (as defined by the Secretary) furnished by the hospital (or by an entity that is wholly owned or operated by the hospital) to the patient during the 3 days preceding the date of the patient's admission to a subsection (d) hospital subject to the IPPS. For a non-subsection (d) hospital (psychiatric hospitals and units, inpatient rehabilitation hospitals and units, long-term care hospitals, children's hospitals, and cancer hospitals), the statutory payment window is 1 day preceding the date of the patient's admission.

Section 102(a)(1) of Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (Pub. L. 111–192, enacted on June 25, 2010) specifies that the term in section 1886(a)(4) of the Act, "other services related to the admission", includes "all services that are not diagnostic services (other than ambulance and maintenance renal dialysis services) for which payment may be made under this title [Title XVIII] that are provided by a hospital (or an entity wholly owned or wholly operated by the hospital) to a patient—(A) on the date of the patient's inpatient admission; or (B) during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of admission unless the hospital demonstrates (in a form and manner, and at a time, specified by the Secretary) that such services are not related (as determined by the Secretary) to such admission." Public Law 111–192 makes no changes to the existing policy regarding billing for diagnostic services.

Under the 3-day (or 1-day) payment window policy, all outpatient diagnostic services furnished to a Medicare beneficiary by a hospital (or an entity wholly owned or operated by the hospital), on the date of a beneficiary's admission or during the 3 days (1 day for a non-subsection (d) hospital) immediately preceding the date of a beneficiary's inpatient hospital admission, must be included on the Part A bill for the beneficiary's inpatient stay at the hospital. All outpatient nondiagnostic services provided by the hospital (or an entity wholly owned or wholly operated) on the date of the inpatient admission or during the 3 days (1 day for a non-subsection (d) hospital) immediately preceding the date of a beneficiary's inpatient hospital admission are deemed related to the admission and must be billed with the inpatient stay unless the hospital attests to specific nondiagnostic services as being unrelated to the hospital claim.

In an interim final rule with comment period issued in the **Federal Register** on August 16, 2010 (75 FR 50346 through 50349), we discussed and made changes to the Medicare regulations pertaining to the 3-day payment window policy in order to comport with the requirements of section 102 of Public Law 111–192. We refer readers to that interim final rule with comment period for further information about the 3-day payment window policy. We have received public comments on the August 16, 2010 interim final rule with comment period, and we plan to address these public comments as well as any public comments we may receive on the proposals in this proposed rule in the FY 2012 IPPS/LTCH PPS final rule.

2. Condition Code 51 (Attestation of Unrelated Outpatient Nondiagnostic Services)

As we stated in the August 16, 2010 interim final rule with comment period (75 FR 50348), we intend to establish a process for hospitals to attest to nondiagnostic services as being unrelated to the hospital claim when a hospital submits an outpatient claim. As part of the process, hospitals would be required to maintain documentation in the beneficiary's medical record to support their claim that the outpatient nondiagnostic services are unrelated to the beneficiary's inpatient admission.

The National Uniform Billing Committee (NUBC) is a committee established by the American Hospital Association and includes the participation of all the major national provider and payer organizations. The NUBC was formed to develop a single billing form and standard data set that could be used nationwide by institutional providers and payers for handling health care claims. The NUBC has provided a mechanism through the establishment of a condition code for a hospital to attest directly on the outpatient claim to specific nondiagnostic services as being clinically unrelated to an inpatient hospital claim (that is, the preadmission diagnostic services are clinically

distinct or independent from the reason for the beneficiary's inpatient admission). As of April 1, 2011, a hospital must add condition code 51 on claims for separately billed outpatient nondiagnostic services furnished on or after June 25, 2010 (the date of enactment of Pub. L. 111–192) if the hospital wishes to attest to nondiagnostic services as being unrelated to the hospital claim. We issued a manual system revision through Change Request #7142, Transmittal 796, on October 29, 2010, instructing CMS contractors to accept condition code 51 on outpatient claims.

3. Applicability of the Payment Window Policy to Services Furnished at Physicians' Practices

We have received several inquiries regarding the applicability of the payment window to preadmission services furnished at hospital-owned or hospital-operated physicians' clinics or practices. The statutory language under section 1886(a)(4) of the Act is clear that the 3-day (or, where applicable, 1-day) payment window policy applies not only to diagnostic and related nondiagnostic services furnished to patients at hospitals but also at entities that are wholly owned or operated by the admitting hospital. In a 1998 final rule on payment for preadmission services (63 FR 6866), we stated, "A hospital-owned or hospital-operated physician clinic or practice is subject to the payment window provision. The technical portion of preadmission diagnostic services performed by the physician clinic or practice must be included on the inpatient bill and may not be billed separately. A physician's professional service is not subject to the window." Thus, we made clear that the term "entities" under this section of the statute includes physicians' clinics or practices. Although the 1998 rule provides specific guidance regarding billing for preadmission diagnostic services furnished at hospital-owned or hospital-operated physician's practices, we had issued no guidelines regarding billing for preadmission nondiagnostic services provided by a hospital-owned or hospital-operated physician's practice, leaving many to assume that the payment window does not apply to such services.

Prior to the June 25, 2010 enactment of section 102(a)(1) of Public Law 111–192, the payment window policy for preadmission nondiagnostic services was rarely applied because the policy required an exact match between the principal ICD–9 CM diagnosis codes for the outpatient services and the inpatient admission. Because of the exact match policy, very few services furnished in a physician's office or clinic that is wholly owned or operated by the hospital would be subject to the policy. However, the statutory change to the payment window policy made by Public Law 111–192 significantly broadened the definition of nondiagnostic services that are subject to the payment window to include any nondiagnostic service that is clinically related to the reason for a patient's inpatient admission, regardless of whether the inpatient and outpatient diagnoses are the same. This statutory change therefore significantly broadens the application of the payment window policy in hospital-owned or hospital-operated physician offices or clinics (that is, clinics that are not provider-based). We note that, under this change, hospitals and hospital-owned or hospital-operated entities must now attest that preadmission nondiagnostic services are not related to an admission using condition code 51 (Attestation of Unrelated Outpatient Nondiagnostic Services) when they submit a claim during the 3-day (or, where applicable, 1-day) preadmission period.

In response to ongoing requests to clarify the applicability of the payment window policy to preadmission nondiagnostic services provided in hospital-owned or hospital-operated physicians' offices or clinics, we are clarifying in this proposed rule that the 3-day (or, where applicable, 1-day) payment window policy applies to both preadmission diagnostic and nondiagnostic services furnished to a patient at physician's practices that are wholly owned or wholly operated by the admitting hospital. For purposes of the payment window, "wholly owned or operated" literally means that the admitting hospital must be the sole owner or the sole operator of the entity providing the preadmission services in order for the payment window policy to apply. A hospital is considered the sole operator of an entity if the hospital has exclusive responsibility for conducting or overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity (we refer readers to the regulations at 42 CFR 412.2(c)(5)(i) and to discussions and examples of wholly owned or operated scenarios in rules issued in the **Federal Register** on January 12, 1994 (59 FR 1656) and February 11, 1998 (63 FR 6865 through 6867)).

In the circumstance where a clinic that is not provider-based meets the definition of being wholly owned or wholly operated by the hospital and the 3-day (or, if applicable, 1-day) payment window applies to related nondiagnostic preadmission services, the hospital's charge on the inpatient claim would include any overhead costs associated with Medicare's physician fee schedule payment. Therefore, it should follow that Medicare's payment to the physician for the physician fee schedule service should be at the lower facility rate, which does not include overhead, staff, equipment, and supplies required to perform the service in the physician's office (rather than the higher nonfacility rate that does include those overhead costs) to avoid paying for the services twice because they are no longer being paid separately under Part B.

Under 42 CFR 414.22(b)(5)(i), Medicare pays physicians using the nonfacility relative value units when services are provided in a physician's office and bases physician payment on the facility relative value units when the physician provides services in a facility, including hospitals, skilled nursing facilities, community mental health centers, and ambulatory surgical centers. Because a hospital-owned or hospital-operated physician practice or clinic that is not provider-based is a nonfacility setting, we will need to change the regulation to specifically provide for Medicare to pay for a service provided in a nonfacility setting at the facility rate in order to comply with section 102(a) of Pub. L. 111–192. We intend to discuss such a proposal in more detail in a future physician fee schedule proposed rule and address how this statutory provision will be implemented in physicians' offices that are wholly owned or wholly operated by the hospital. In all circumstances, we would expect the hospital to inform the physician offices and clinics where the hospital is the sole owner or sole operator and when an inpatient admission occurs.

P. Proposed Changes to MS–DRGs Subject to the Postacute Care Transfer Policy

1. Background

Existing regulations at § 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy, set forth in § 412(f), provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a

graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is double the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases are also eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to the fixed-loss outlier threshold for nontransfer cases (adjusted for geographic variations in costs), divided by the geometric mean length of stay for the MS–DRG, and multiplied by the length of stay for the case, plus one day.

We established the criteria set forth in § 412.4 for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the DRG's total number of discharges and proportion of short-stay discharges to postacute care exceed the 55th percentile for all DRGs, CMS will apply the postacute care transfer policy to that DRG and to any other MS–DRG that shares the same base DRG. In the preamble to the FY 2006 final rule (70 FR 47419), we stated that "we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific DRG."

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a reduced per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6)). For an MS–DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. DRGs that are part of an MS–DRG group must meet DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

2. Proposed Changes to the Postacute Care Transfer MS–DRGs

Based on our annual review of MS–DRGs, we have identified a number of MS–DRGs that should be included on the list of MS–DRGs subject to the postacute care transfer policy. As we discuss in section III.G. of this proposed rule, in response to public comments and based on our analysis of FY 2010 MedPAR claims data, we are proposing to make several changes to MS–DRGs to better capture certain severity of illness levels, to be effective for FY 2012. Specifically, we are proposing to modify the assignment of the autologous bone marrow transplants now assigned to MS–DRG 015 (Autologous Bone Marrow Transplant) to capture the severity levels of "with CC/MCC" and "without CC/MCC." We are proposing to establish two new MS–DRGs (proposed MS–DRGs 016 and 017 (Autologous Bone Marrow Transplant with MCC/CC and without MCC/CC, respectively) to replace MS–DRG 015. We also are proposing to establish three new MS–DRGs to capture three severity of illness levels for skin debridement—proposed MS–DRG 570 (Skin Debridement with MCC); proposed MS–DRG 571 (Skin Debridement with CC); and proposed MS–DRG 572 (Skin Debridement without CC/MCC). In addition, we are proposing to move the codes for rechargeable dual array deep brain stimulation (codes 02.93 and 86.98) to MS–DRGs 023 and 024 (Craniotomy with Major Device Implant/Acute Complex CNS PDX, with MCC and without MCC, respectively) where similar devices are currently assigned. We are proposing to move two procedure codes that either repair a thoracic aneurysm or place a stent graft (codes 38.45 and 39.73) out of MS–DRG 237 and 238 (Major Cardiovascular Procedures w MCC or Thoracic Aortic Aneurysm Repair, and Major Cardiovascular Procedures with MCC and without MCC, respectively). We are proposing to assign these two codes to MS–DRGs 219, 220, and 221 (Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC, with CC, and without CC, respectively). We are proposing to add a procedure code for partial gastrectomy (43.89) to MS–DRGs 619, 620, and 621 (O.R. Procedure for Obesity with MCC, with CC, and without CC/MCC, respectively). A discussion of these proposed changes can be found in section II.G. of the preamble of this proposed rule.

In light of these proposed changes to the MS–DRGs, according to the regulations under § 412.4(c), we evaluated these proposed FY 2012 MS–DRGs against the general postacute care transfer policy criteria using the FY 2010 MedPAR data. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). We note that these proposed changes to the MS–DRGs can result in interactive effects between MS–DRGs and in cases moving from existing MS–DRGs to the new proposed MS–DRGs, and that our review reflects this as well. As a result of our review, we are proposing to update the list of MS–DRGs that are subject to the postacute care transfer policy to include the proposed new MS–DRGs 570, 571, and 572 for FY 2012. (These MS–DRGs are reflected in Table 5, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, and are also listed in the tables at the end of this section.)

In addition, based on our evaluation of the proposed FY 2012 MS–DRGs using the FY 2010 Med PAR data, we have identified the following two existing MS–DRGs that meet the criteria to be subject to the postacute care transfer policy for FY 2012: MS–DRGs 023 (Craniotomy with Major Device Implant or Acute Complex CNS PDX with MCC) and MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS PDX without MCC). We are proposing to add these two MS–DRGs to the list of MS–DRGs that are subject to the postacute care transfer policy for FY 2012. The following table lists the respective criteria for each MS–DRG that we are proposing to add to the postacute transfer policy list.

Further, based on our evaluation of the proposed FY 2012 MS–DRGs using the FY 2010 Med PAR data, we have determined that MS–DRGs 228 (Other Cardiothoracic Procedures with MCC), 229 (Other Cardiothoracic Procedures with CC), 230 (Other Cardiothoracic Procedures without CC/MCC), 640 (Miscellaneous Disorders of Nutrition, Metabolism, Fluids/Electrolytes with MCC), and 641 (Miscellaneous

Disorders of Nutrition, Metabolism, Fluids/Electrolytes without MCC) no longer meet the postacute care transfer criteria. Therefore, we are proposing that they be removed from the list of DRGs subjected to the postacute care transfer policy, effective FY 2012. We refer readers to the bolded text in the following table to see which criteria were not met in our analysis for each MS–DRG removed from the postacute care transfer policy list.

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LIST OF MS-DRGs CHANGING POSTACUTE CARE TRANSFER POLICY STATUS IN FY 2012

MS-DRG	MS-DRG Title	Total cases	Postacute care transfers (55th percentile: 1,586)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 7.9591%)	Postacute transfer policy status
023	CRANIO W MAJOR DEV IMPL/ACUTE COMPLEX CNS PDX W MCC OR CHEMO IMPLANT	4,601	2,215	370	8.04%	YES
024	CRANIO W MAJOR DEV IMPL/ACUTE COMPLEX CNS PDX W/O MCC	1,726	**992***	161	9.33%	YES**
228	OTHER CARDIOTHORACIC PROCEDURES W MCC	1,929	**1,215***	450	23.33%	NO
229	OTHER CARDIOTHORACIC PROCEDURES W CC	2,381	**1,315***	418	17.56%	NO
230	OTHER CARDIOTHORACIC PROCEDURES W/O CC/MCC	641	**226***	11	**1.72%***	NO
570	SKIN DEBRIDEMENT W MCC	5,211	4,007	1577	30.26%	YES
571	SKIN DEBRIDEMENT W CC	5,574	3,851	1099	19.72%	YES
572	SKIN DEBRIDEMENT W/O CC/MCC	2,542	**1,384***	226	8.89%	YES**
640	MISC DISORDERS OF NUTRITION,METABOLISM,FLUIDS/ELECTROLYTES W MCC	57,197	22,571	3618	**6.33%***	NO
641	MISC DISORDERS OF NUTRITION,METABOLISM,FLUIDS/ELECTROLYTES W/O MCC	169,353	69,590	5167	**3.05%***	NO

* Indicates a current postacute care transfer policy criterion that the MS-DRG did not meet.

** As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS-DRGs that share the same base MS-DRG shall all meet postacute care transfer policy if any one of the MS-DRGs that share that same base MS-DRG qualifies.

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Finally, we have determined that MS–DRGs 216 (Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC), 217 (Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC), and 218 (Cardiac Valve & Other Major Cardiothoracic Procedure without CC/MCC) meet the criteria for the special payment methodology. Therefore, we are proposing that they would be subject to the DRG special payment methodology, effective FY 2012.

LIST OF MS-DRGs CHANGING DRG SPECIAL PAYMENT POLICY STATUS IN FY 2012

MS-DRG	MS-DRG Title	Geometric mean length of stay	Average charges of 1-day discharges	50% of average charges for all cases within MS-DRG	Special pay policy status
216	CARDIAC VALVE & OTH MAJ CARDIOTHORACIC PROC W CARD CATH W MCC	14.2497327	$164,838	125,398	YES
217	CARDIAC VALVE & OTH MAJ CARDIOTHORACIC PROC W CARD CATH W CC	9.518336312	$126,655	84,669	YES
218	CARDIAC VALVE & OTH MAJ CARDIOTHORACIC PROC W CARD CATH W/O CC/MCC	7.102572558	$0	0	YES*

* As described in the policy at 42 CFR 412.4(d)(6)(iv), MS-DRGs that share the same base MS-DRG shall meet DRG special payment policy if any one of the MS-DRGs that share that same base MS-DRG qualifies.

Q. Hospital Services Furnished Under Arrangements

For purposes of Medicare payment, section 1861(b) of the Act defines "inpatient hospital services" in part as "* * * the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital—

(1) Bed and board;

(2) Such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients * * *; and

(3) Such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements;"

We note that the statute specifies that "routine services," for example, bed, board, nursing and other related services, except those specified at paragraph (3) of section 1861(b) of the Act are to be provided by "the hospital," and not just "a hospital." Similarly, our implementing regulations at 42 CFR 409.12 indicate that Medicare pays for "nursing and related services, use of hospital * * * facilities, and medical social services as * * * inpatient hospital services or inpatient CAH services * * * only if those services are ordinarily furnished by the hospital or CAH." Consistent with the statute, only with regard to other diagnostic or therapeutic services do the regulations at 42 CFR 409.16 state that Medicare will also pay for these services if furnished "by others under arrangements made by the hospital or CAH."

However, it has come to our attention that some providers in the hospital community may have interpreted our instructions under section 2118 (Cost of Services Furnished under Arrangement) of the Provider Reimbursement Manual, Part I (PRM–I), relating to payment for routine services to allow additional services to be provided under arrangements. Some providers have interpreted the provision of the paragraph on "Routine Services" relating to services provided "under arrangement" under section 2118 of the PRM–I to mean that even routine services described in sections 1861(b)(1) and (b)(2) of the Act, which are normally provided to hospital inpatients by the hospital, can be provided by an outside entity under arrangement.

To the extent that our manual provisions could be read to allow hospitals to furnish such "routine services" "under arrangements," we are now proposing a change to limit the services a hospital may provide under arrangement to reflect the statutory definition of "inpatient hospital services" and the implementing regulations. Under our proposed policy, if routine services, that is, services described in sections 1861(b)(1) and (b)(2) of the Act, are provided in the hospital, they are considered as being provided "by the hospital." We believe that this proposal is consistent with the statute because the statutory language specifying that the routine services described in sections 1861(b)(1) and (b)(2) of the Act be provided "by the hospital" suggests that the hospital is required to exercise professional responsibility over the services, including quality controls. In situations

in which certain routine services are provided under arrangements "in the hospital," for example, contracted nursing services, we believe the arrangement generally results in the hospital exercising the same level of control over those services as the hospital does in situations in which the services are provided by the hospital's salaried employees. Therefore, if these services are provided in the hospital to its inpatients, we consider the services as being provided by the hospital. However, if these services are provided outside the hospital, the services are considered as being provided under arrangement, and not by the hospital. That is, consistent with the statute, only therapeutic and diagnostic services can be provided under arrangement. If we finalize this proposed policy, we will change the provisions of section 2118 of the PRM–I accordingly.

V. Proposed Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services "in accordance with a prospective payment system established by the Secretary." Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the Federal fiscal year (FY) 1992 IPPS final rule (56 FR 43358), in which we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.) The basic methodology for determining capital prospective payments using the Federal rate is set forth in § 412.312 of the regulations. For the purpose of calculating capital payments for each discharge, currently the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

B. Exception Payments

The regulations at § 412.348(f) provide that a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. This policy was originally established for hospitals during the 10-year transition period, but as we discussed in the FY 2003 IPPS final rule (67 FR 50102), we revised the regulations at § 412.312 to specify that payments for extraordinary circumstances are also made for cost reporting periods after the transition period (that is, cost reporting periods beginning on or after October 1, 2001). Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

During the transition period, under §§ 412.348(b) through (e), eligible hospitals could receive regular exception payments. These exception payments guaranteed a hospital a minimum payment percentage of its Medicare allowable capital-related costs depending on the class of the hospital (§ 412.348(c)), but were available only during the 10-year transition period. After the end of the transition period, eligible hospitals can no longer receive this exception payment. However, even after the transition period, eligible hospitals receive additional payments under the special exceptions provisions at § 412.348(g), which guarantees all eligible hospitals a minimum payment of 70 percent of its Medicare allowable capital-related costs provided that special exceptions payments do not exceed 10 percent of total capital IPPS payments. Hospitals eligible for special exceptions payments are required to submit documentation to the fiscal intermediary or MAC indicating the completion date of their project. Special exceptions payments may be made only for the 10 years from the cost reporting year in which the hospital completes its qualifying project, and the hospital must have completed the project no later than the hospital's cost reporting period beginning before October 1, 2001. Thus, an eligible hospital may receive special exceptions payments for up to 10 years beyond the end of the capital IPPS transition period. Under this limitation on the period for special exceptions payments at § 412.348(g)(7) of the regulations, FY 2012 is the final year hospitals can receive special exceptions payments. (For more detailed information regarding the special exceptions policy under § 412.348(g), we refer readers to the FY 2002 IPPS final rule (66 FR 39911 through 39914) and the FY 2003 IPPS final rule (67 FR 50102).)

C. New Hospitals

Under the IPPS for capital-related costs, § 412.300(b) of the regulations defines a new hospital as a hospital that has operated (under current or previous ownership) for less than 2 years. For example, the following hospitals are not considered new hospitals: (1) A hospital that builds new or replacement facilities at the same or another location, even if coincidental with a change of ownership, a change in management, or a lease arrangement; (2) a hospital that closes and subsequently reopens; (3) a hospital that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years; and (4) a hospital that changes its status from a hospital that is excluded from the IPPS to a hospital that is subject to the capital IPPS. For more detailed information, we refer readers to the FY 1992 IPPS final rule (56 FR 43418). During the 10-year transition period, a new hospital was exempt from the capital IPPS for its first 2 years of operation and was paid 85 percent of its reasonable costs during that period. Originally, this provision was effective only through the transition period and, therefore, ended with cost reporting periods beginning in FY 2002. Because, as discussed in the FY 2003 IPPS final rule (67 FR 50101), we believe that special protection to new hospitals is also appropriate even after the transition period, we revised the regulations at § 412.304(c)(2) to provide that, for cost reporting periods beginning on or after October 1, 2002, a new hospital (defined under § 412.300(b)) is paid 85 percent of its Medicare allowable capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. (We refer readers to the FY 2003 IPPS final rule (67 FR 50101 through 50102) for a detailed discussion of the special payment provisions for new hospitals under the capital IPPS after the 10-year transition period.)

D. Hospitals Located in Puerto Rico

Section 412.374 of the regulations provides for the use of a blended payment amount for prospective payments for capital-related costs to hospitals located in Puerto Rico. Accordingly, under the capital IPPS, we compute a separate payment rate specific to Puerto Rico hospitals using the same methodology used to compute the national Federal rate for capital-related costs. In general, hospitals located in Puerto Rico are paid a blend of the applicable capital IPPS Puerto Rico rate and the applicable capital IPPS Federal rate.

Prior to FY 1998, hospitals in Puerto Rico were paid a blended capital IPPS rate that consisted of 75 percent of the capital IPPS Puerto Rico specific rate and 25 percent of the capital IPPS Federal rate. However, effective October 1, 1997 (FY 1998), in conjunction with the change to the operating IPPS blend percentage for hospitals located in Puerto Rico required by section 4406 of Public Law 105–33, we revised the methodology for computing capital IPPS payments to hospitals in Puerto Rico to be based on a blend of 50 percent of the capital IPPS Puerto Rico rate and 50 percent of the capital IPPS Federal rate. Similarly, in conjunction with the change in operating IPPS payments to hospitals located in Puerto Rico for FY 2005 required by section 504 of Public Law 108–173, we again revised the methodology for computing capital IPPS payments to hospitals located in Puerto Rico to be based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate effective for discharges occurring on or after October 1, 2004.

E. Proposed Changes for FY 2012: MS–DRG Documentation and Coding Adjustment

1. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize patient severity of illness in Medicare payment rates. Adoption of the MS–DRGs resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, there are 747 MS–DRGs and we are proposing 4 additional MS–DRGs for FY 2012.) By increasing the number of DRGs and more fully taking into account patient severity of illness in Medicare payment rates, the MS–DRGs encourage hospitals to change their documentation and coding of patient diagnoses. In that same final rule with comment period (72 FR 47183), we indicated that we believe the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for changes in documentation and coding. Accordingly, we established adjustments to both the national operating standardized amount and the national capital Federal rate to eliminate the estimated effect of changes in documentation and coding resulting from the adoption of the MS–DRGs that do not reflect real changes in case-mix. Specifically, we established prospective documentation and coding adjustments of −1.2 percent for FY 2008, −1.8 percent for FY 2009, and −1.8 percent for FY 2010. However, to comply with section 7(a) of Public Law 110–90, enacted on September 29, 2007, in a final rule published in the **Federal Register** on November 27, 2007 (72 FR 66886 through 66888), we modified the documentation and coding adjustment for FY 2008 to −0.6 percent, and consequently revised the FY 2008 IPPS operating and capital payment rates, factors, and thresholds accordingly, with these revisions effective October 1, 2007.

For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent instead of the −1.8 percent adjustment established in the FY 2008 IPPS final rule with comment period. As discussed in the FY 2008 IPPS final rule with comment period (72 FR 48447 and 48733 through 48774), we applied an additional documentation and coding adjustment of −0.9 percent to the FY 2009 IPPS national standardized amounts and the national capital Federal rate. The documentation and coding adjustments established in the FY 2009 IPPS final rule, as amended by Public Law 110–90, are cumulative. As a result, the −0.9 percent documentation and coding adjustment in FY 2009 was in addition to the −0.6 percent adjustment in FY 2008, yielding a combined effect of −1.5 percent. (For additional details on the development and implementation of the documentation and coding adjustments for FY 2008 and FY 2009, we refer readers to section II.D. of this preamble and the following rules published in the **Federal Register**: August 22, 2007 (72 FR 47175 through 47186 and 47431 through 47432); November 27, 2007 (72 FR 66886 through 66888); and August 19, 2008 (73 FR 48447 through 48450 and 48773 through 48775).)

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24092 through 24101), we presented the results of a retrospective evaluation of the FY 2008 data for claims paid through December 2008. We sought public comment on our methodology and analysis and our proposal to apply a prospective adjustment to address the effect of documentation and coding changes unrelated to changes in real case-mix in FY 2008. In addition, we sought public comment on addressing in the FY 2011 rulemaking cycle any effect of documentation and coding changes that do not reflect real changes in case-mix for discharges occurring during FY 2009. However, after consideration of the public comments received on the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, consistent with the application of the documentation and coding adjustment to the operating IPPS standardized amounts, we determined that it would be appropriate to postpone the adoption of any additional documentation and coding adjustments to the capital IPPS rates until a full analysis of FY 2009 case-mix changes could be completed (74 FR 43926 through 43928).

For the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24014), we performed a thorough retrospective evaluation of the most recent available claims data, and the results of this evaluation were used by our actuaries to determine any necessary payment adjustments beyond the cumulative −1.5 percent adjustment that has already been applied to the national capital Federal rate to ensure budget neutrality for the implementation of MS–DRGs. Specifically, we performed a retrospective evaluation of the FY 2009 claims data updated through December 2009 using the same analysis methodology as we did for FY 2008 claims in the FY 2010 IPPS/RY 2010 LTCH PPS proposed and final rules. Based on this evaluation, our actuaries determined that the implementation of the MS–DRG system resulted in a 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. We also noted our intent to update our analysis with FY 2009 data on claims paid through March 2009 (sic) for the FY 2011 IPPS/LTCH PPS final rule. (We note that the March 2009 update date for claims paid data in the proposed rule should have stated March 2010.)

As intended, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50355), we updated our analysis with FY 2009 data on claims paid through March 2010 in that final rule. For the FY 2011 IPPS/LTCH PPS final rule, applying the same analysis methodology

as we did for the proposed rule to an FY 2009 claims data updated through March 2010 verified the 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. The 5.4 percent estimate of the cumulative effect of changes in documentation and coding under the MS–DRG system that did not reflect real changes in case-mix for FYs 2008 and 2009 exceeded the cumulative −1.5 percent prospective documentation and coding adjustment that had already been applied to the national capital Federal rate by 3.9 percentage points (5.4 percent minus 1.5 percent). Therefore, an additional cumulative adjustment of −3.9 percent to the national capital Federal rate would be necessary to eliminate the full effect of the documentation and coding changes due to the adoption of the MS–DRGs on future payments.

Therefore, in that same final rule, under the Secretary's broad authority under section 1886(g) of the Act, consistent with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, we implemented an adjustment to the FY 2011 national capital Federal rate of −2.9 percent to account for part of the effect of the estimated changes in documentation and coding changes under the MS–DRG system that occurred in FYs 2008 and 2009 that did not reflect real changes in case-mix. We also established that we will leave the −2.9 percent adjustment in place for subsequent fiscal years to account for the effect of that documentation and coding change in subsequent years. Furthermore, we stated our intention to address the remaining estimated adjustment to the national capital Federal rate of −1.0 percent (that is, the estimated effect of documentation and coding changes under the MS–DRG system of −5.4 percent minus the existing −0.6 percent and −0.9 percent adjustments and the −2.9 percent adjustment for FY 2011) in future rulemaking cycles.

2. Proposed Prospective MS–DRG Documentation and Coding Adjustment to the National Capital Federal Rate for FY 2012 and Subsequent Years

We continue to believe that it is appropriate to make adjustments to the capital IPPS rates to eliminate the effect of any documentation and coding changes as a result of the implementation of the MS–DRGs. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 accurately reflected the changes due to documentation and coding that occurred in those years. As noted in section V.A. of this preamble, under section 1886(g) of the Act, the Secretary has broad authority in establishing and implementing the IPPS for acute-care hospital inpatient capital-related costs (that is, the capital IPPS). We have consistently stated since the initial implementation of the MS–DRG system that we do not believe it is appropriate for Medicare expenditures under the capital IPPS to increase due to MS–DRG related changes in documentation and coding. Accordingly, we believe that it is appropriate under the Secretary's broad authority under section 1886(g) of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, to make adjustments to the national capital Federal rate to eliminate the full effect of the documentation and coding changes resulting from the adoption of the MS–DRGs. We believe that this is appropriate because, in absence of such adjustments, the effect of the documentation and coding changes resulting from the adoption of the MS–DRGs results in inappropriately high capital IPPS payments because that portion of the increase in aggregate payments is not due to an increase in patient severity of illness (and costs).

As discussed above, based on our retrospective evaluation of the FY 2009 claims, our actuaries determined that implementation of the MS–DRG system resulted in a 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. To date, we have made adjustments to the national capital Federal rate to account for 4.4 percent (that is, −0.6 percent in FY 2008, −0.9 percent in FY 2009, and −2.9 percent in FY 2011) of the estimated 5.4 percent documentation and coding effect. Thus, our current estimate of the remaining adjustment to the national capital Federal rate is −1.0 percent to account for the effect of documentation and coding changes under the MS–DRG system for FYs 2008 and 2009.

In this proposed rule, under the Secretary's broad authority under section 1886(g) of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, consistent with the intention we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50357), we are proposing to reduce the national capital Federal rate in FY 2012 by −1.0 percent to account for the remainder of the cumulative effect of the estimated changes in documentation and coding under the MS–DRG system in FYs 2008 and 2009 that did not reflect real changes in case-mix. Furthermore, consistent with the documentation and coding adjustments we have made in the past, we are proposing to leave this proposed −1.0 percent adjustment in place for subsequent fiscal years to account for the effect in FY 2012 and subsequent years. As explained above, this proposed −1.0 percent adjustment accounts for the remainder of our current estimate of the cumulative effect of documentation and coding changes under the MS–DRG system for FYs 2008 and 2009 of −5.4 percent minus the existing −0.6 percent, −0.9 percent, and −2.9 percent adjustments.

3. Documentation and Coding Adjustment to the Puerto Rico-Specific Capital Rate

Under § 412.74, Puerto Rico hospitals are currently paid based on 75 percent of the national capital Federal rate and 25 percent of the Puerto Rico-specific capital rate. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50358 through 50359), we discussed the retrospective evaluation of the FY 2009 claims data from the March 2010 update of the MedPAR file of hospitals located in Puerto Rico using the same methodology used to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals. This analysis shows that the change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico was approximately 2.6 percent. (As discussed in that same final rule, the Puerto Rico-specific capital rate was not adjusted for the cumulative effects of documentation and coding changes in FY 2008 or FY 2009.) We also explained that we continue to believe that such an adjustment is appropriate because all hospitals have the same financial incentives for documentation and coding improvements, and the same ability to benefit from the resulting increase in aggregate payments that do not reflect real changes in case-mix.

Given this case-mix increase due to changes in documentation and coding under the MS–DRGs, consistent with the adjustment we made to the FY 2011 national capital Federal rate (discussed above) and consistent with our adjustment to the FY 2011 Puerto Rico-specific standardized amount, under the

Secretary's broad authority under section 1886(g) of the Act, we established an adjustment to the Puerto Rico-specific capital rate of −2.6 percent in FY 2011 for the cumulative increase in case-mix due to changes in documentation and coding under the MS–DRGs for FYs 2008 and 2009. In addition, consistent with our implementation of other prospective MS–DRG documentation and coding adjustments to the capital Federal rate and operating IPPS standardized amounts, we established that we will leave that −2.6 percent adjustment in place for subsequent fiscal years in order to ensure that changes in documentation and coding resulting from the adoption of the MS–DRGs do not lead to an increase in aggregate payments not reflective of an increase in real case-mix in subsequent years. The −2.6 percent adjustment to the capital Puerto Rico-specific rate that we made in FY 2011 reflects the entire amount of our current estimate of the effects of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico. Consequently, in this proposed rule, we are not proposing to make any additional adjustments to the capital Puerto Rico-specific rate for FY 2012 for the effect of documentation and coding that did not reflect real changes in case-mix.

F. Other Proposed Changes for FY 2012

The proposed annual update to the capital IPPS national Federal and Puerto Rico-specific rates, as provided for at § 412.308(c), for FY 2012 is discussed in section III. of the Addendum to this proposed rule.

VI. Proposed Changes for Hospitals Excluded From the IPPS

A. Excluded Hospitals

Historically, hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a)) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount was multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to all categories of excluded providers, which included rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and IPPS-excluded cancer hospitals.

Payment to children's hospitals and cancer hospitals that are excluded from the IPPS continues to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. (We note that, in accordance with § 403.752(a) of the regulations, RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

We are proposing that the FY 2012 rate-of-increase percentage to be applied to the target amount for cancer and children's hospitals and RNHCIs be the estimated FY 2012 percentage increase in the IPPS operating market basket, estimated to be 2.8 percent. Beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's and cancer hospitals. As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), with IRFs, IPFs, and LTCHs being paid under their own PPS, the remaining number of providers being paid based on reasonable cost subject to a ceiling (that is, children's hospitals, 11 cancer hospitals, and RNHCIs) is too small and the cost report data are too limited to be able to create a market basket solely for these hospitals. For FY 2012, we are proposing to continue to use the IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs for the reasons discussed in the FY 2006 IPPS final rule.

Therefore, we are proposing to use the revised and rebased FY 2006-based IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs for FY 2012. Based on IHS Global Insight, Inc.'s 2011 first quarter forecast, with historical data through the 2010 fourth quarter, we are estimating that the FY 2012 update to the IPPS operating market basket would be 2.8 percent (that is, the estimate of the market basket rate-of-increase). (We are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2012.)

We note that IRFs, IPFs, and LTCHs, which were paid previously under the reasonable cost methodology, now receive payment under their own prospective payment systems, in accordance with changes made to the statute. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provided transition periods of varying lengths during which time a portion of the prospective payment was based on cost-based reimbursement rules under Part 413. (However, certain providers do not receive a transition period or may elect to bypass the transition period as applicable under 42 CFR part 412, subparts N, O, and P.) We note that the various transition periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section IV. of the Addendum to this proposed rule for the specific proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2012. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

B. Critical Access Hospital (CAH) Payment for Ambulance Services

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs) under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and that meet the CAH conditions of participation under 42 CFR Part 485, Subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413. Section 1834(l) of the Act sets forth the payment rules for ambulance services. Generally, payment to ambulance providers and suppliers for ambulance services are made under the ambulance fee schedule. Section 205 of Public Law 106–554 (BIPA) amended section 1834(l) of the Act by adding a paragraph (8) to that section, which provides that the Secretary shall pay the reasonable costs incurred in furnishing ambulance services if such services are furnished by a CAH (as defined in section 1861(mm)(1) of the Act), or by an entity that is owned and operated by a CAH, but only if the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of the CAH. The term "provider of ambulance services" includes all Medicare-participating providers that submit claims under Medicare for ambulance services (for example, hospitals, CAHs, skilled nursing facilities (SNFs), and home health agencies (HHAs)). The term "supplier of ambulance services" is defined as an

entity that provides ambulance services and that is independent of any Medicare-participating or non-Medicare-participating provider. Section 205 was effective for services furnished on or after December 21, 2000. Regulations implementing section 1834(l)(8) of the Act are set forth at 42 CFR 413.70(b)(5).

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50361), we implemented section 3128(a) of the Affordable Care Act, which amended section 1834(l)(8) of the Act by inserting "101 percent of" before "the reasonable costs." As such, section 3128(a) increased payment for ambulance services furnished by a qualifying CAH or entity owned and operated by a CAH to 101 percent of reasonable costs, effective for cost reporting periods beginning on or after January 1, 2004. We amended the regulations at § 413.70(b)(5)(i) to conform to this statutory change by stating that, effective for cost reporting periods beginning on or after January 1, 2004, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity furnishing those services is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity.

2. Requirement for CAH Ambulance Within a 35-Mile Location of a CAH or Entity

Section 413.70(b)(5) of the existing regulations states that payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is "the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity". However, the statutory language at section 1834(l)(8) of the Act states that a CAH is eligible to be paid based on 101 percent of reasonable cost for ambulance services furnished by the CAH or by an entity that is owned and operated by a CAH, but only if the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such CAH. Because the statute only requires that there be no other provider or supplier of ambulance services within a 35-mile drive of the CAH and does not address whether there is another provider or supplier of ambulance services within a 35-mile drive of the CAH-owned and operated entity, we believe that the existing regulation is not consistent with the plain reading of the statutory language at section 1834(l)(8) of the Act. In addition, we believe the plain reading of the statutory language at section 1834(l)(8) of the Act does not address the situation where there is no provider or supplier of ambulance services within a 35-mile drive of the CAH, but there is a CAH-owned and operated entity furnishing ambulance services that is more than a 35-mile drive from the CAH, thus creating a "gap" in the statutory language. That is, the statutory language does not address the situation where the entity that is owned and operated by the CAH is located *more* than a 35-mile drive from the CAH.

In order to ensure that the regulations are consistent with the plain language of section 1834(l)(8) of the Act, we are proposing to revise § 413.70(b)(5)(i) by adding a new paragraph (C) to state that, effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or by a CAH-owned and operated entity is 101 percent of reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH (Figure 1). Under this proposed change, the CAH-owned and operated entity would be paid 101 percent of reasonable cost for its ambulance services only if there is no other provider or supplier of ambulance services within a 35-mile drive of the CAH. However, if there is a provider or supplier of ambulance services located within a 35-mile drive of the CAH (Figure 2), the CAH-owned and operated entity would not be paid at 101 percent of reasonable cost, but instead would be paid under the ambulance fee-schedule.

In addition, we are proposing to establish a policy that would address the "gap" in the statutory language, that is, where the CAH-owned and operated entity furnishing ambulance services is more than a 35-mile drive from the CAH, but there is no other provider or supplier of ambulance services located within a 35-mile drive of the CAH. We are proposing to include in the proposed new paragraph (C) of § 413.70(b)(5)(i) a provision which states that, effective for cost reporting periods beginning on or after October 1, 2011, if there is no provider or supplier of ambulance services within a 35-mile drive of the CAH but there is a CAH-owned and operated entity that is more than a 35-mile drive from the CAH, the CAH-owned and operated entity would be paid at 101 percent of reasonable cost for its ambulance services as long as that entity is the closest provider or supplier of ambulance services to the CAH (Figure 3). Allowing the CAH-owned and operated entity to be paid at 101 percent of reasonable cost if there is no other provider or supplier of ambulance services that is closer to the CAH is consistent with the original purpose of section 1834(l)(8) of the Act, which was intended to help ensure an adequate level of ambulance services in areas served by CAHs. The statute allows for reasonable cost-based payment only if there is no other provider or supplier of ambulance services within a 35-mile drive of the CAH. If there is another provider or supplier of ambulance services located within a 35-mile drive of the CAH, the statute does not allow for payment to the CAH or a CAH-owned and operated entity at 101 percent of reasonable cost because there is an adequate level of ambulance services available. Accordingly, where a CAH-owned and operated entity is located more than a 35-mile drive from the CAH, we are proposing to allow payment at 101 percent of reasonable cost only if there is no other provider or supplier of ambulance services located closer to the CAH. If there is a closer provider or supplier of ambulance services, that closer provider or supplier would also be assuring an adequate level of ambulance services in the area served by the CAH, and there would be no need to pay the CAH-owned and operated entity at 101 percent of reasonable cost in order to ensure access to ambulance services. Therefore, if the CAH-owned and operated entity (located more than a 35-mile drive from the CAH) is not the closest provider or supplier of ambulance services to the CAH (Figure 4), the CAH-owned and operated entity would be reimbursed under the ambulance fee schedule.

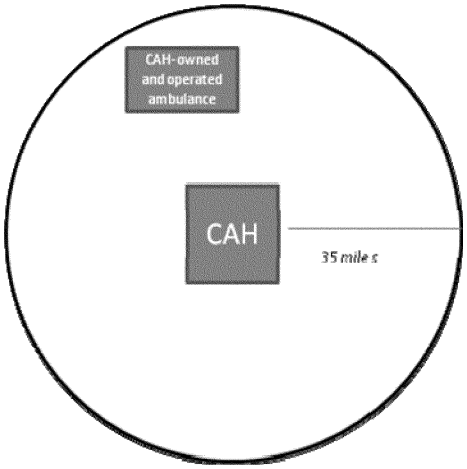

Figure 1:
The CAH-owned and operated entity would be paid at 101 percent of reasonable cost for its ambulance service because there is no other provider or supplier of ambulance services within a 35-mile drive of the CAH.

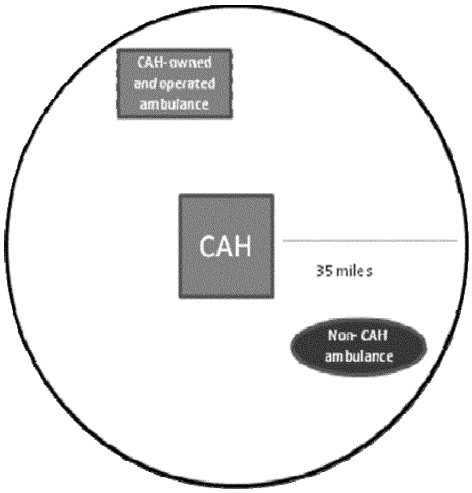

Figure 2:
The CAH-owned and operated entity would be paid under the ambulance fee schedule for its ambulance services because the CAH-owned and operated entity is not the only provider or supplier of ambulance services located within a 35-mile drive of the CAH.

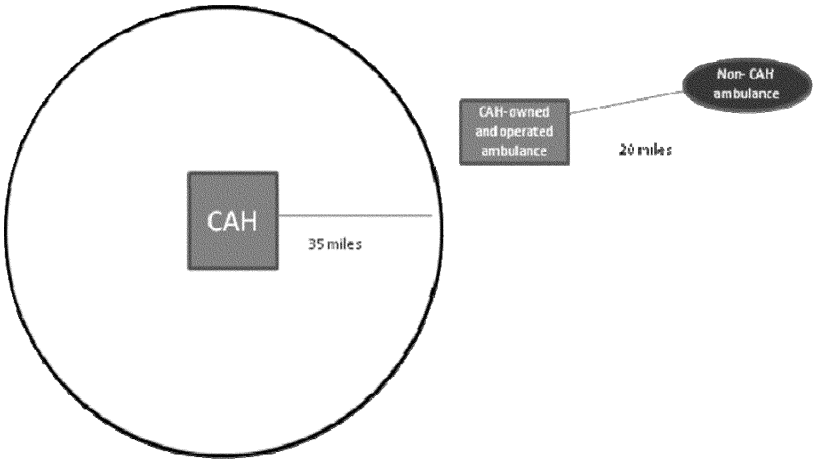

Figure 3:

The CAH-owned and operated entity would be paid at 101 percent of reasonable cost for its ambulance services because even though the CAH-owned and operated entity is more than a 35-mile drive from the CAH, it is the closest provider or supplier of ambulance services to the CAH.

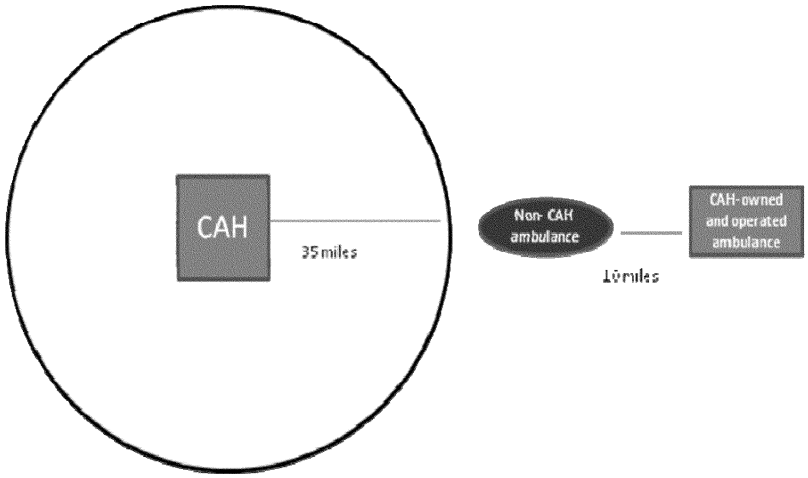

Figure 4:

The CAH-owned and operated entity would receive payment under the ambulance fee schedule for its ambulance service because there is another provider or supplier of ambulance services that is closer to the CAH than the CAH-owned and operated entity.

In summary, we are proposing to amend § 413.70(b)(5)(i) by adding a new paragraph (C) to state that, effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or by a CAH-owned and operated entity is 101 percent of reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. In addition, we are proposing to include in the proposed new § 413.70(b)(5)(i)(C) a provision to state that, effective for cost reporting periods beginning on or after October 1, 2011, if there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH, but there is a CAH-owned and operated entity more than a 35-mile drive from the CAH, the CAH-owned and operated entity would be paid at 101 percent of reasonable cost for its ambulance services as long as that entity is the closest provider or supplier of ambulance services to the CAH. We also are making a conforming change to § 413.70(b)(5)(i)(B) to make the effective date of that paragraph consistent with the effective date of the new proposed paragraph (C).

VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2012

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Social Security Act (the Act), effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines a LTCH as "a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days." Section 1886(d)(1)(B)(iv)(II) of the Act also provides an alternative definition of LTCHs: specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (LOS) (as determined by the Secretary of Health and Human Services (the Secretary)) of greater than 20 days and has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997.

Section 123 of the BBRA requires the PPS for LTCHs to be a "per discharge" system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA)

(Pub. L. 97–248) for payments for inpatient services provided by a LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR Part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in section VIII. of this preamble, when we refer to discharges, the intent is to describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period. During this 5-year transition period, a LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts. However, effective for cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR Part 412, Subpart O also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the June 6, 2003 **Federal Register**, we published a final rule that set forth the FY 2004 annual update of the payment rates for the Medicare PPS for inpatient hospital services furnished by LTCHs (68 FR 34122). It also changed the annual period for which the payment rates were to be effective, such that the annual updated rates were effective from July 1 through June 30 instead of from October 1 through September 30. We referred to the July through June time period as a "long-term care hospital rate year" (LTCH PPS rate year). In addition, we changed the publication schedule for the annual update to allow for an effective date of July 1. The payment amounts and factors used to determine the annual update of the LTCH PPS Federal rate are based on a LTCH PPS rate year. In the past, while the LTCH payment rate updates were effective July 1, the annual update of the DRG classifications and relative weights for LTCHs continued to be linked to the annual adjustments of the acute care hospital inpatient DRGs and were effective each October 1.

As discussed in detail in the RY 2009 LTCH PPS final rule (73 FR 26797 through 26798), we again changed the schedule for the annual updates of the LTCH PPS Federal payment rates beginning with RY 2010. We consolidated the rulemaking cycle for the annual update of the LTCH PPS Federal payment rates and description of the methodology and data used to calculate these payment rates with the annual update of the MS–LTC–DRG classifications and associated weighting factors for LTCHs so that the updates to the rates and the relative weights now occur on the same schedule and appear in the same publication. As a result, the updates to the rates and the relative weights are now effective on October 1 (on a Federal fiscal year schedule), and the annual updates to the LTCH PPS Federal rates are no longer published with a July 1 effective date.

Public Law 110–173 (MMSEA), enacted on December 29, 2007, included provisions that have various effects on the LTCH PPS. In addition to amending section 1861 of the Act to add a subsection (ccc) which provided an additional definition of LTCHs, Public Law 110–173 also required the Secretary to submit, no later than 18 months after the date of enactment of the law, a report to Congress on a study of national long-term care hospital facility and patient criteria that included "recommendations for such legislation and administrative actions, including timelines for the implementation of LTCH patient criteria or other actions, as the Secretary determines appropriate." The payment policy provisions under sections 114(c)(1) and (c)(2) of Public Law 110–173 focused on providing 3 years of relief for certain LTCHs from the percentage threshold payment adjustment policy at 42 CFR 412.534 and 412.536. However, because of the original implementation schedule of those sections of the regulations, the payment provisions had varying timeframes of applicability (73 FR 29701 through 29704). In addition, section 114(c)(3) of Public Law 110–173 provided that the Secretary shall not apply, for the 3-year period beginning on the date of enactment of the Act the revision to the short-stay outlier (SSO) policy that was finalized in the RY 2008 LTCH PPS final rule (72 FR 26904 and 26992). In addition, section 114(c)(4) of Public Law 110–173 provided that the Secretary shall not, for the 3-year period beginning on the date of enactment of the Act, make the one-time adjustment to the payment rates provided for in § 412.523(d)(3) or any similar provision (73 FR 26800 through 26804). The statute also provided that the base rate for RY 2008 be the same as the base rate for RY 2007 (the revised base rate, however, does not apply to discharges occurring on or after July 1, 2007, and before April 1, 2008) (73 FR 24875 through 24877). Section 114(d) of Public Law 110–173 established a 3-year moratorium (with specified exceptions) on the establishment and classification of new LTCHs, LTCH satellites, and on the increase in the number of LTCH beds in existing LTCHs or satellite facilities. Finally, section 114(f) of Public Law 110–173 provided for an expanded review of medical necessity for admission and continued stay at LTCHs.

In the RY 2009 LTCH PPS final rule (73 FR 26804 through 26812), we established the applicable Federal rates for RY 2009, consistent with section 1886(m)(2) of the Act as amended by Public Law 110–173. We also revised the regulations at § 412.523(d)(3) to change the methodology for the one-time budget neutrality adjustment and to comply with section 114(c)(4) of Public Law 110–173. Other policy revisions that were necessary as a result of the statutory changes of Public Law 110–173 were addressed in separate interim final rules with comment period (73 FR 24871 and 73 FR 29699). In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43976 through 43990), we addressed all of the public comments received and finalized these two interim final rules with comment period.

Section 4302 of the ARRA, Public Law 111–5, enacted on February 17, 2009, included several amendments to the provisions set forth in section 114 of Public Law 110–173. Specifically, section 4302(a) modified the effective

dates of the provisions of section 114(c) of Public Law 110–173, described above, and added an additional category of LTCHs or satellite facilities that would not be subject to the percentage threshold payment adjustment at § 412.536 for a 3-year period. In addition, section 4302(a)(2)(A) of Public Law 111–5 added "grandfathered" satellites (specified in § 412.22(h)(3)(i) of the regulations) to those "applicable" LTCHs (specified in § 412.534(g) of the regulations) originally granted relief under section 114(c) of Public Law 110–173. We issued instructions to the fiscal intermediaries and MACs interpreting the provisions of section 4302 of Public Law 111–5 (Change Request 6444). In addition, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43990 through 43992), we implemented the provisions of section 4302 of Public Law 111–5 through an interim final rule with comment period. We received one piece of timely correspondence regarding the provisions of section 4302 of Public Law 111–5 that were implemented through the interim final rule with comment period that was included in the FY 2010 IPPS/RY 2010 LTCH PPS final rule. We addressed this public comment and finalized the interim final rule with comment period in section VII.E. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50399).

As discussed in the FY 2011 IPPS/LTCH PPS final rule, a number of the provisions of the Affordable Care Act affected the policies, payment rates and factors under the LTCH PPS. Specifically, section 1886(m)(3)(A)(ii) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for each of rate years 2010 through 2019, any annual update to the standard Federal rate shall be reduced by the other adjustment specified in new section 1886(m)(4) of the Act. Furthermore, section 1886(m)(3)(A)(i) of the Act specifies that, for rate year 2012 and subsequent rate years, any annual update to the standard Federal rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(m)(3)(A)(ii) and sections 1886(m)(4)(A) and (B) of the Act require a 0.25 percentage point reduction for rate year 2010 and a 0.50 percentage point reduction for rate year 2011. Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. Furthermore, section 3401(p) of the Affordable Care Act specifies that the amendments made by section 3401(c) of such Act shall not apply to discharges occurring before April 1, 2010 (75 FR 50387 through 50390). Sections 3106 and 10312 of the Affordable Care Act together provide for a 2-year extension to the payment policies applicable to LTCHs and LTCH satellite facilities set forth in sections 114(c) and (d)(1) of the MMSEA, as amended by the ARRA. Specifically, sections 3106 and 10312 of the Affordable Care Act together result in the phrase "3-year period" being replaced with the phrase "5-year period" each place it appears in sections 114(c) and (d)(1) of MMSEA, as amended by the ARRA. As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50399 through 50400), sections 3106 and 10312 of the Affordable Care Act, which amended sections 114(c) and (d)(1) of the MMSEA, as amended by the ARRA, result in the following:

- An additional 2-year delay in the application of the SSO payment adjustment, which would have applied the additional payment option of an "IPPS comparable" payment to LTCHs for certain SSO cases where the covered length of stay is less than or equal to the "IPPS comparable threshold." Therefore, the Secretary will not apply this SSO payment adjustment for the 5-year period beginning on the date of enactment of MMSEA (December 29, 2007).
- An additional 2-year delay in the one-time prospective budget neutrality adjustment to the standard Federal rate (§ 412.523(d)(3)). Thus, the Secretary is precluded from making the one-time adjustment to standard Federal rate until December 29, 2012.
- An increase from 3 years to 5 years to the timeframes set forth in section 114(c) of the MMSEA as amended by the ARRA, thereby extending for an additional 2 years the delay in the application of the 25-percent payment threshold policy for certain LTCHs and LTCH satellite facilities (§§ 412.534 and 412.536), and extending for an additional 2 years, the increased percentage thresholds outlined at section 114(c)(2) of the MMSEA as amended by the ARRA.
- Additional 2-year extensions of the moratorium on the establishment of new LTCHs and LTCH satellite facilities and the moratorium on the increase of LTCH beds in existing LTCHs or satellite facilities as provided by section 114(d) of the MMSEA as amended by the ARRA. In general, section 114(d) of the MMSEA as amended by the ARRA precluded the establishment and classification of new LTCHs or LTCH satellite facilities or additional beds from being added to existing LTCHs or LTCH satellite facilities unless one of the specified exceptions to the particular moratorium was met.

2. Criteria for Classification as a LTCH

a. Classification as a LTCH

Under the existing regulations at § 412.23(e)(1) and (e)(2)(i), which implement section 1886(d)(1)(B)(iv)(I) of the Act, to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare and must have an average Medicare inpatient length of stay (LOS) of greater than 25 days. Alternatively, § 412.23(e)(2)(ii) states that for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c), and therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR Part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b–1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). In the RY 2005 LTCH PPS final rule (69 FR 25676), we clarified that the discussion of beneficiary liability in the August 30, 2002 final rule was not meant to establish rates or payments for, or define Medicare-eligible expenses. Under § 412.507, if the Medicare payment to

the LTCH is the full LTC–DRG payment amount, as consistent with other established hospital prospective payment systems, a LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87 and for items and services as specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the SSO threshold is exceeded. Therefore, if the Medicare payment was for a SSO case (§ 412.529) that was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH could also charge the beneficiary for services delivered on those uncovered days (§ 412.507).

4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191). Section 3 of the ASCA requires that the Medicare Program deny payment under Part A or Part B for any expenses incurred for items or services "for which a claim is submitted other than in an electronic form specified by the Secretary." Section 1862(h) of the Act (as added by section 3(a) of the ASCA) provides that the Secretary shall waive such denial in two specific types of cases and may also waive such denial "in such unusual cases as the Secretary finds appropriate" (68 FR 48805). Section 3 of the ASCA operates in the context of the HIPAA regulations, which include, among other provisions, the transactions and code sets standards requirements codified as 45 CFR parts 160 and 162, Subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct certain electronic healthcare transactions according to the applicable transactions and code sets standards.

B. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2012

1. Background

Section 123 of the BBRA requires that the Secretary implement a PPS for LTCHs (that is, a per discharge system with a diagnosis-related group (DRG)-based patient classification system reflecting the differences in patient resources and costs). Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine "the feasibility and the impact of basing payment under such a system [the long-term care hospital (LTCH) PPS] on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients, as well as the use of the most recently available hospital discharge data."

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system (that is, the CMS DRGs) that was utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the "long-term care diagnosis-related groups (LTC–DRGs)." Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect "the differences in patient resource use * * *" of LTCH patients (section 123(a)(1) of the BBRA (Pub. L. 106–113)).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development and implementation and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR Part 412, Subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.) We believe the MS–DRGs (and by extension, the MS–LTC–DRGs) represent a substantial improvement over the previous CMS DRGs in their ability to differentiate cases based on severity of illness and resource consumption.

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. As described in section II.G. of this preamble, for FY 2012 we are proposing to delete one MS–DRG and create two new MS–DRGs for a net gain of one MS–DRG. If this proposal is adopted, we would have a total of 751 MS–DRG groupings. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In a departure from the IPPS, and as discussed in greater detail below in section VII.B.3.f. of this preamble, we are proposing to continue to use low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 LTCH cases) in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. For purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we are proposing to group all of the low-volume MS–LTC–DRGs into five quintiles based on average charge per discharge. (A detailed discussion of the initial development and application of the quintile methodology appears in the August 30, 2002 LTCH PPS final rule (67 FR 55978).) We also are proposing to account for adjustments to payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG). Furthermore, we are proposing to make adjustments to account for nonmonotonically increasing weights, when necessary. That is, theoretically, cases under the MS–LTC–DRG system that are more severe require greater expenditure of medical care resources and will result in higher average charges

such that, in the severity levels within a base MS–LTC–DRG, the weights should increase monotonically with severity from the lowest to highest severity level. (We discuss nonmonotonicity in greater detail and our proposed methodology to adjust the FY 2011 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights in section VII.B.3.g. (Step 6) of this preamble.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted above in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–9–CM procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKG), or minor surgical procedures (for example, biopsy of skin and subcutaneous tissue (procedure code 86.11)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge and that payment varies by the MS–LTC–DRG to which a beneficiary's stay is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Through FY 2010, the number of secondary or additional diagnoses and the number of surgical procedures considered for MS–DRG assignment was limited to eight and six, respectively. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127), we established that, for claims submitted on the 5010 format beginning January 1, 2011, we would increase the capacity to process diagnosis and procedure codes up to 25 diagnoses and 25 procedures. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. We refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule for a complete discussion of this change (75 FR 50127).

Upon the discharge of the patient from a LTCH, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). HIPAA Transactions and Code Sets Standards regulations at 45 CFR Parts 160 and 162 require that no later than October 16, 2003, all covered entities must comply with the applicable requirements of Subparts A and I through R of Part 162. Among other requirements, those provisions direct covered entities to use the ASC X12N 837 Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, and the applicable standard medical data code sets for the institutional health care claim or equivalent encounter information transaction (45 CFR 162.1002 and 45 CFR 162.1102). For additional information on the ICD–9–CM Coding System, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47241 through 47243 and 47277 through 47281). We also refer readers to the detailed discussion on correct coding practices in the August 30, 2002 LTCH PPS final rule (67 FR 55981 through 55983). Additional coding instructions and examples are published in the *Coding Clinic for ICD–9–CM,* a product of the American Hospital Association. (We refer readers to section II.G.13. of this preamble for additional information on the annual revisions to the ICD–9–CM codes.)

With respect to the ICD–9–CM coding system, we have been discussing the conversion to the ICD–10–CM and the ICD–10–PCS coding systems for many years. As is discussed in detail in section II.G.11. of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50122 through 50127) and in section III.G.13 of this proposed rule, the ICD–10 coding systems applicable to hospital inpatient services will be implemented on October 1, 2013. In order for the industry to make the necessary conversions from ICD–9–CM to ICD–10–CM and ICD–10–PCS, we proposed, through the ICD–9–CM Coordination and Maintenance Committee, to consider a moratorium on updates to the ICD–9–CM and ICD–10 coding sets. We refer readers to section II.G.13. of this preamble for additional information on the adoption of the ICD–10–CM and ICD–10–PCS systems.

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), individual DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into three, two, or one level, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication and comorbidity (MCC). We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

Medicare contractors (that is, fiscal intermediaries and MACs) enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further development (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the Medicare contractor determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the Medicare contractor and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes

and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2012

As specified by our regulations at § 412.517(a), which requires that the MS–LTC–DRG classifications and relative weights be updated annually and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2011, through September 30, 2012 (FY 2012) consistent with the proposed changes to specific MS–DRG classifications presented in section II.G. of this proposed rule (that is, proposed GROUPER Version 29.0). Therefore, the proposed MS–LTC–DRGs for FY 2012 presented in this proposed rule are the same as the proposed MS–DRGs that would be used under the IPPS for FY 2012. In addition, because the proposed MS–LTC–DRGs for FY 2012 are the same as the proposed MS–DRGs for FY 2012, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed Version 29.0 of the GROUPER discussed in section II.G. of the preamble of this proposed rule, including the proposed changes to the MCE software and proposed changes to the ICD–9–CM coding system, also would be applicable under the LTCH PPS for FY 2012.

3. Development of the Proposed FY 2012 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

As we stated in the August 30, 2002 LTCH PPS final rule (67 FR 55984), one of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly. To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment system rate by the applicable relative weight in determining payment to LTCHs for each case.

Although the adoption of the MS–LTC–DRGs resulted in some modifications of existing procedures for assigning weights in cases of zero volume and/or nonmonotonicity (as discussed in the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550)), the basic methodology for developing the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule continues to be determined in accordance with the general methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in a MS–LTC–DRG with a relative weight of 2 will, on average, cost twice as much to treat as cases in a MS–LTC–DRG with a relative weight of 1.

b. Development of the Proposed MS–LTC–DRG Relative Weights for FY 2012

Beginning with the FY 2008 update, we established a budget neutrality requirement for the annual update to the MS–LTC–DRG classifications and relative weights at § 412.517(b) (in conjunction with § 412.503), such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the classification and relative weight changes (RY 2008 LTCH PPS final rule (72 FR 26882 through 26884)). Consistent with § 412.517(b), we are proposing to apply a two-step budget neutrality methodology, which is based on the current year MS–LTC–DRG classifications and relative weights. (For additional information on the established two-step budget neutrality methodology, we refer readers to the FY 2008 IPPS final rule (72 FR 47295 through 47296).) Thus, for this proposed rule, the annual update to the MS–LTC–DRG classifications and relative weights for FY 2012 are based on the FY 2011 MS–LTC–DRG classifications and relative weights established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50613 through 50627).

c. Data

In this proposed rule, to calculate the proposed MS–LTC–DRG relative weights for FY 2012, we are proposing to obtain total charges from FY 2010 Medicare LTCH bill data from the December 2010 update of the FY 2010 MedPAR file, which are the best available data at this time, and to use the proposed Version 29.0 of the GROUPER to classify LTCH cases. We also are proposing that if more recent data become available, we would to use those data and the finalized Version 29.0 of the GROUPER in establishing the FY 2012 MS–LTC–DRG relative weights in the final rule.

Consistent with our historical methodology, we are proposing to exclude the data from LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, as is the case with the IPPS, Medicare Advantage (Part C) claims are now included in the MedPAR files (74 FR 43808). Consistent with IPPS policy, we are proposing to continue to exclude such claims in the calculations for the relative weights under the LTCH PPS that are used to determine payments for fee-for-service Medicare claims. Specifically, we are proposing to remove any claims from the MedPAR files that have a GHO Paid indicator value of "1," which effectively removes Medicare Advantage claims from the relative weight calculations (73 FR 48532). Therefore, in the development of the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule, we are proposing to exclude the data of 13 all-inclusive rate providers and the 2 LTCHs that are paid in accordance with demonstration projects that had claims in the FY 2010 MedPAR file, as well as any Medicare Advantage claims.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients and rehabilitation and wound care. Some case types (DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, we are proposing to continue to use a hospital-specific relative value

(HSRV) methodology to calculate the proposed MS–LTC–DRG relative weights for FY 2012. We believe this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, we are proposing to reduce the impact of the variation in charges across providers on any particular proposed MS–LTC–DRG relative weight by converting each LTCH's charge for a case to a relative value based on that LTCH's average charge.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each case to hospital-specific relative charge values and then adjust those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for a LTCH is its case-mix, so it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the cases it treats relative to the complexity of the cases treated by all other LTCHs (the average case-mix of all LTCHs).

In accordance with our established methodology, we are proposing to continue to standardize charges for each case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described below in section VII.B.3.g. (step 3) of the preamble of this proposed rule) by the average adjusted charge for all cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case (67 FR 55989).

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at a LTCH with higher average costs than they would at a LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. Because we standardize charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a $10,000 charge for a case at a LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at a LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the Proposed MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of DRGs based on volume of cases within specific MS–LTC–DRGs. MS–LTC–DRGs with at least 25 cases are each assigned a unique relative weight; low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 cases based on a given year's claims data) are grouped into quintiles (as described below) and assigned the relative weight of the quintile. No-volume MS–LTC–DRGs (that is, no cases in the given year's claims data were assigned to those MS–LTC–DRGs) are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail below). In this proposed rule, we are proposing to continue to utilize these same three categories of MS–LTC–DRGs for purposes of determining the proposed MS–LTC–DRG relative weights for FY 2012. (We provide in-depth discussions of our proposed policy regarding weight-setting for proposed low-volume MS–LTC–DRGs in section VII.B.3.f. of the preamble of this proposed rule and for proposed no-volume MS–LTC–DRGs, under Step 5 in section VII.B.3.g. of the preamble of this proposed rule.)

As also noted above, while the LTCH PPS and the IPPS use the same patient classification system, the methodology that is used to set the DRG relative weights for use in each payment system differs because the overall volume of cases in the LTCH PPS is much less than in the IPPS. In general, consistent with our existing methodology, we are proposing to use the following steps to determine the proposed FY 2012 MS–LTC–DRG relative weights: (1) If a proposed MS–LTC–DRG has at least 25 cases, it is assigned its own proposed relative weight; (2) if a proposed MS–LTC–DRG has between 1 and 24 cases, it is assigned to a quintile for which we compute a proposed relative weight for all of the proposed MS–LTC–DRGs assigned to that quintile; and (3) if a proposed MS–LTC–DRG has no cases, it is cross-walked to another proposed MS–LTC–DRG based upon clinical similarities to assign an appropriate proposed relative weight (as described below in detail in Step 5 of section VII.B.3.g. of this preamble). Furthermore, in determining the proposed FY 2012 MS–LTC–DRG relative weights, when necessary, we are proposing to make adjustments to account for nonmonotonicity, as discussed in greater detail below in Step 6 of section VII.B.3.g. of this preamble. We refer readers to the discussion in the FY 2010 IPPS/RY LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Proposed Low-Volume MS–LTC–DRGs

In order to account for proposed MS–LTC–DRGs with low volume (that is, with fewer than 25 LTCH cases), consistent with our existing methodology we are proposing, for purposes of determining the proposed FY 2012 MS–LTC–DRG relative weights, to continue to employ the quintile methodology for proposed low-volume MS–LTC–DRGs, such that we group those proposed "low-volume MS–LTC–DRGs" (that is, proposed MS–LTC–DRGs that contained between 1 and 24 cases annually) into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995 and 72 FR 47283 through 47288). In determining the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule, in cases where the initial assignment of a proposed low-volume MS–LTC–DRG to quintiles resulted in nonmonotonicity within a base-DRG, in order to ensure appropriate Medicare payments, consistent with our historical methodology, we are proposing to make adjustments to the treatment of proposed low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail below in section VII.B.3.g. (Step 6) in this preamble.

In this proposed rule, using LTCH cases from the December 2010 update of the FY 2010 MedPAR file, we identified 277 MS–LTC–DRGs that contained between 1 and 24 cases. This list of proposed MS–LTC–DRGs was then divided into one of the 5 low-volume quintiles, each containing a minimum of 55 proposed MS–LTC–DRGs (277/5 = 55 with 2 proposed MS–LTC–DRG as the remainder). We assigned a proposed low-volume MS–LTC–DRG to a specific

low-volume quintile by sorting the proposed low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Furthermore, because the number of MS–LTC–DRGs with less than 25 cases is not evenly divisible by 5, the average charge of the low-volume quintile was used to determine which of the proposed low-volume quintiles would contain the 2 additional proposed low-volume MS–LTC–DRGs. Specifically, after organizing the MS–LTC–DRGs by ascending order by average charge, we assigned the first fifth (1st through 55th) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The proposed MS–LTC–DRGs with the highest average charge cases would be assigned into Quintile 5. Because the average charge of the 56th proposed low-volume MS–LTC–DRG in the sorted list is closer to the average charge of the 55th proposed low-volume MS–LTC–DRG (assigned to Quintile 1) than to the average charge of the 57th proposed low-volume MS–LTC–DRG (assigned to Quintile 2), we are proposing to assign it to Quintile 1 (such that Quintile 1 would contain 56 proposed low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). This process was repeated through the remaining proposed low-volume MS–LTC–DRGs so that 3 of the 5 low-volume quintiles contain 55 proposed MS–LTC–DRGs (Quintiles 2, 3, and 5) and the other 2 low-volume quintiles contain 56 proposed MS–LTC–DRGs (Quintiles 1 and 4). Table 13A, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet, lists the composition of the proposed low-volume quantitles for MS–LTC–DRGs for FY 2012.

Accordingly, in order to determine the proposed FY 2012 relative weights for the proposed MS–LTC–DRGs with low volume, we are proposing to use the 5 low-volume quintiles described above. The proposed composition of each of the 5 low-volume quintiles shown in the chart below was used in determining the proposed FY 2012 MS–LTC–DRG relative weights (as shown in Table 11 listed in section VI. of the Addendum to this proposed rule and available via the Internet). We determined a proposed relative weight and (geometric) average length of stay for each of the 5 low-volume quintiles using the methodology that we are proposing to apply to the proposed MS–LTC–DRGs (25 or more cases), as described in section VII.B.3.g. of the preamble of this proposed rule. We are proposing to assign the same relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a proposed low volume of LTCH cases will vary in the future. We are proposing to use the best available claims data in the MedPAR file to identify proposed low-volume MS–LTC–DRGs and to calculate the proposed relative weights based on our methodology.

We note that we will continue to monitor the volume (that is, the number of LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the proposed MS–LTC–DRG relative weights result in appropriate payment for such cases and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the Proposed FY 2012 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing, in general, to determine the FY 2012 MS–LTC–DRG relative weights based on our existing methodology. For additional information on the original development of this methodology, and modifications to it since the adoption of the MS–LTC–DRGs, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55995) and the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43951 through 43966).

In summary, for FY 2012, to determine the proposed FY 2012 MS–LTC–DRG relative weights, we are proposing to group LTCH cases to the appropriate proposed MS–LTC–DRG, while taking into account the proposed low-volume quintile (as described above). After grouping the cases to the appropriate MS–LTC–DRG (or low-volume quintile), we are proposing to calculate the proposed FY 2012 relative weights by first removing statistical outliers and cases with a length of stay of 7 days or less (as discussed in greater detail below). Next, we are proposing to adjust the number of cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases (step 3 below). After removing statistical outliers (step 1 below) and cases with a length of stay of less than 8 days (step 2 below), the SSO adjusted discharges and corresponding charges were then used to calculate proposed "relative adjusted weights" for each proposed MS–LTC–DRG (or proposed low-volume quintile) using the HSRV method.

Below we discuss in detail the steps for calculating the proposed FY 2012 MS–LTC–DRG relative weights. We note that, as we stated in section VII.B.3.c. of this preamble, we excluded the data of all-inclusive rate LTCHs, LTCHs that are paid in accordance with demonstration projects, and any Medicare Advantage claims in the FY 2010 MedPAR file.

Step 1—Remove statistical outliers.

The first step in the calculation of the proposed FY 2012 MS–LTC–DRG relative weights is to remove statistical outlier cases. Consistent with our historical relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each proposed MS–LTC–DRG. These statistical outliers are removed prior to calculating the proposed relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the proposed relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among the proposed MS–LTC–DRGs. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove cases with a length of stay of 7 days or less.

The proposed MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in a LTCH because these stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH. If we were to include stays of 7 days or less in the computation of the proposed FY 2012 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a LTCH by including data from these very short-stays. Therefore, consistent with our historical relative weight methodology, in determining the proposed FY 2012 MS–LTC–DRG relative weights, we removed LTCH cases with a length of stay of 7 days or less. (For additional information on this step of the relative weight methodology,

we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 3—Adjust charges for the effects of SSOs.

After removing cases with a length of stay of 7 days or less, we are left with cases that have a length of stay of greater than or equal to 8 days. As the next step in the calculation of the proposed FY 2012 MS–LTC–DRG relative weights, consistent with our historical relative weight methodology, we are proposing to adjust each LTCH's charges per discharge for those remaining cases for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503).

We are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the proposed MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the proposed MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the proposed MS–LTC–DRG.

Counting SSO cases as full discharges with no adjustment in determining the proposed FY 2012 MS–LTC–DRG relative weights would lower the proposed FY 2012 MS–LTC–DRG relative weight for affected proposed MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a proposed MS–LTC–DRG. This would result in an "underpayment" for non-SSO cases and an "overpayment" for SSO cases. Therefore, we are proposing to adjust for SSO cases under § 412.529 in this manner because it results in more appropriate payments for all LTCH cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the proposed FY 2012 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed FY 2012 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each LTCH case, we are proposing to calculate a hospital-specific relative charge value by dividing the SSO adjusted charge per discharge (see Step 3) of the LTCH case (after removing the statistical outliers (see Step 1)) and LTCH cases with a length of stay of 7 days or less (see Step 2) by the average charge per discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce a proposed adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 is used for each LTCH.

For each proposed MS–LTC–DRG, we are proposing to calculate the proposed FY 2012 relative weight by dividing the average of the adjusted hospital-specific relative charge values (from above) for the proposed MS–LTC–DRG by the overall average hospital-specific relative charge value across all cases for all LTCHs. Using these recalculated proposed MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its cases (that is, its case-mix) is calculated by dividing the sum of all the LTCH's proposed MS–LTC–DRG relative weights by its total number of cases. The LTCHs' hospital-specific relative charge values above were multiplied by these hospital-specific case-mix indexes. These hospital-specific case-mix adjusted relative charge values were then used to calculate a new set of proposed MS–LTC–DRG relative weights across all LTCHs. This iterative process was continued until there was convergence between the weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a proposed FY 2012 relative weight for MS–LTC–DRGs with no LTCH cases.

As we stated above, we are proposing to determine the proposed FY 2012 relative weight for each proposed MS–LTC–DRG using total Medicare allowable total charges reported in the best available LTCH claims data (that is, the December 2010 update of the FY 2010 MedPAR file for this proposed rule). Using these data, we identified a number of proposed MS–LTC–DRGs for which there were no LTCH cases in the database, such that no patients who would have been classified to those proposed MS–LTC–DRGs were treated in LTCHs during FY 2010 and, therefore, no charge data were available for these proposed MS–LTC–DRGs. Thus, in the process of determining the proposed MS–LTC–DRG relative weights, we were unable to calculate proposed relative weights for the proposed MS–LTC–DRGs with no LTCH cases using the methodology described in Steps 1 through 4 above. However, because patients with a number of the diagnoses under these proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we are proposing to assign a proposed relative weight to each of the proposed no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of "transplant" MS–LTC–DRGs and "error" MS–LTC–DRGs, as discussed below). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

In general, we are proposing to determine proposed FY 2012 relative weights for the proposed MS–LTC–DRGs with no LTCH cases in the FY 2010 MedPAR file used in this proposed rule (that is, proposed "no-volume" MS–LTC–DRGs) by cross-walking each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG with a calculated proposed relative weight (determined in accordance with the proposed methodology described above). Then, the proposed "no-volume" MS–LTC–DRG was assigned the same relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was cross-walked (as described in greater detail below).

Of the 751 proposed MS–LTC–DRGs for FY 2012, we identified 237 proposed MS–LTC–DRGs for which there were no LTCH cases in the database (including the 8 "transplant" proposed MS–LTC–DRGs and 2 "error" proposed MS–LTC–DRGs). As stated above, we are proposing to assign relative weights for each of the 237 proposed no-volume MS–LTC–DRGs (with the exception of the 8 "transplant" proposed MS–LTC–DRGs and the 2 "error" proposed MS–LTC–DRGs, which are discussed below) based on clinical similarity and relative costliness to one of the remaining 514 (751—237= 514) proposed MS–LTC–DRGs for which we were able to determine proposed relative weights based on FY 2010 LTCH claims data using the steps described above. (For the remainder of this discussion, we refer to the proposed "cross-walked" MS–LTC–DRGs as the proposed MS–LTC–DRGs to which we crosswalk one of the 237 proposed "no volume" MS–LTC–DRGs for purposes of determining a proposed relative weight.) Then, we assigned the proposed no-volume MS–LTC–DRG the proposed relative weight of the proposed cross-walked MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

For this proposed rule, we are proposing to crosswalk the proposed no-volume MS–LTC–DRG to a proposed MS–LTC–DRG for which there were LTCH cases in the FY 2010 MedPAR file, and to which it is similar clinically

in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. We evaluated the relative costliness in determining the applicable proposed MS–LTC–DRG to which a proposed no-volume MS–LTC–DRG was cross-walked in order to assign an appropriate proposed relative weight for the proposed no-volume MS–LTC–DRGs in FY 2012. (For more detail on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the proposed no-volume MS–LTC–DRGs in FY 2012, the proposed relative weights assigned based on the proposed cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on similar clinical similarity and relative costliness, generally require equivalent relative resource use.

We are proposing to then assign the proposed relative weight of the proposed cross-walked MS–LTC–DRG as the proposed relative weight for the proposed no-volume MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the proposed no-volume MS–LTC–DRG and the proposed cross-walked MS–LTC–DRG) have the same proposed relative weight for FY 2012. We note that if the proposed cross-walked MS–LTC–DRG had 25 cases or more, its proposed relative weight, which was calculated using the proposed methodology described in Steps 1 through 4 above, was assigned to the proposed no-volume MS–LTC–DRG as well. Similarly, if the proposed MS–LTC–DRG to which the no-volume MS–LTC–DRG is cross-walked had 24 or less cases and, therefore, was designated to one of the low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable low-volume quintile to the proposed no-volume MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the proposed no-volume MS–LTC–DRG and the proposed cross-walked MS–LTC–DRG) have the same proposed relative weight for FY 2012. (As we noted above, in the infrequent case where nonmonotonicity involving a proposed no-volume MS–LTC–DRG results, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing relative weights.)

For this proposed rule, a list of the proposed no-volume MS–LTC–DRGs and the proposed MS–LTC–DRG to which it is cross-walked (that is, the proposed cross-walked MS–LTC–DRG) for FY 2012 is shown in Table 13B, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet.

To illustrate this methodology for determining the proposed relative weights for the FY 2012 MS–LTC–DRGs with no LTCH cases, we are providing the following example, which refers to the proposed no-volume MS–LTC–DRGs crosswalk information for FY 2012 provided in Table 13B.

Example: There were no cases in the FY 2010 MedPAR file used for this proposed rule for MS–LTC–DRG 61 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that MS–LTC–DRG 70 (Nonspecific Cebrovascular Disorders with MCC) was similar clinically and based on resource use to MS–LTC–DRG 61. Therefore, we assigned the same proposed relative weight of MS–LTC–DRG 70 of 0.8062 for FY 2012 to MS–LTC–DRG 61 (Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available vie the Internet).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume of LTCH cases based on the system will vary in the future. We are proposing to use the most recent available claims data in the MedPAR file to identify proposed no-volume MS–LTC–DRGs and to determine the proposed relative weights in this proposed rule.

Furthermore, for FY 2012, consistent with our historical relative weight methodology, we are proposing to establish proposed MS–LTC–DRG relative weights of 0.0000 for the following transplant proposed MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (proposed MS–LTC–DRG 1); Heart Transplant or Implant of Heart Assist System without MCC (proposed MS–LTC–DRG 2); Liver Transplant with MCC or Intestinal Transplant (proposed MS–LTC–DRG 5); Liver Transplant without MCC (proposed MS–LTC–DRG 6); Lung Transplant (proposed MS–LTC–DRG 7); Simultaneous Pancreas/Kidney Transplant (proposed MS–LTC–DRG 8); Pancreas Transplant (proposed MS–LTC–DRG 10); and Kidney Transplant (proposed MS–LTC–DRG 652). This is because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these proposed eight transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these proposed MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).)

Step 6—Adjust the proposed FY 2012 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

As discussed earlier in this section, the MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as "without CC/MCC." When data do not support the creation of three severity levels, the base DRG is subdivided into either two levels or the base DRG is not subdivided. The two-level subdivisions could consist of the DRG with CC/MCC and the DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the DRG with MCC and the DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the "without CC/MCC" MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the "with CC/MCC" MS–LTC–DRG (in the case of a two-level split) or both the "with CC" and the "with MCC" MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and will result in higher average charges. Therefore, in the three severity levels, proposed relative weights should increase by severity, from lowest to highest. If the proposed relative weights decrease as severity decreased (that is, if within a base proposed MS–LTC–DRG, a proposed MS–LTC–DRG with CC has a higher proposed relative weight than one with MCC, or the proposed MS–LTC–DRG without CC/MCC has a higher proposed relative weight than either of the others), they are nonmonotonic. We

continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Consequently, in determining the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule, consistent with our historical methodology we are proposing to combine proposed MS–LTC–DRG severity levels within a base proposed MS–LTC–DRG for the purpose of computing a proposed relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule by applying this methodology are denoted in Table 11, which is listed in sectin VI. of the Addendum to this proposed rule and is available via the Internet.

Step 7— Calculate the proposed FY 2012 budget neutrality factor.

As we established in the RY 2008 LTCH PPS final rule (72 FR 26882), under the broad authority conferred upon the Secretary to develop the LTCH PPS under section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554, beginning with the MS–LTC–DRG update for FY 2008, the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes (§ 412.517(b) in conjunction with § 412.503). (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in accordance with § 412.503). Under the budget neutrality requirement at § 412.517(b), for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to update the MS–LTC–DRG classifications and relative weights for FY 2012 based on the most recent available LTCH data, and to apply a budget neutrality adjustment in determining the proposed FY 2012 MS–LTC–DRG relative weights.

To ensure budget neutrality in the proposed update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. In this proposed rule, in the first step of our proposed MS–LTC–DRG budget neutrality methodology, we are proposing for FY 2012 to calculate and apply a proposed normalization factor to the recalibrated proposed relative weights (the result of Steps 1 through 6 above) to ensure that estimated payments are not influenced by changes in the composition of case types or the changes to the classification system. That is, the proposed normalization adjustment is intended to ensure that the recalibration of the proposed MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average CMI.

To calculate the proposed normalization factor for FY 2012 (the first step of our budget neutrality methodology), we are proposing to use the following three steps: (1.a.) We used the most recent available LTCH claims data (FY 2010) and grouped them using the proposed FY 2012 GROUPER (Version 29.0) and the proposed recalibrated FY 2012 MS–LTC–DRG relative weights (determined in steps 1 through 6 of the Steps for Determining the Proposed FY 2012 MS–LTC–DRG Relative Weights above) to calculate the average CMI; (1.b.) we grouped the same LTCH claims data (FY 2010) using the FY 2011 GROUPER (Version 28.0) and FY 2011 MS–LTC–DRG relative weights and calculated the average CMI; and (1.c.) we computed the ratio of these average CMIs by dividing the average CMI for FY 2011 (determined in Step 1.b.) by the proposed average CMI for FY 2012 (determined in step 1.a.). In determining the proposed MS–LTC–DRG relative weights for FY 2012, each proposed recalibrated MS–LTC–DRG relative weight was multiplied by 1.11482 in the first step of the budget neutrality methodology, which produced "normalized relative weights."

In this proposed rule, in the second step of our proposed MS–LTC–DRG budget neutrality methodology, we are proposing to determine a budget neutrality factor to ensure that estimated aggregate LTCH PPS payments (based on the most recent available LTCH claims data) after reclassification and recalibration (that is, the proposed FY 2012 MS–LTC–DRG classifications and relative weights) are equal to estimated aggregate LTCH PPS payments before reclassification and recalibration (that is, the FY 2011 MS–LTC–DRG classifications and relative weights). Accordingly, consistent with our existing methodology, we are proposing to use FY 2010 discharge data to simulate payments and compare estimated aggregate LTCH PPS payments using the FY 2011 MS–LTC–DRGs and relative weights to estimate aggregate LTCH PPS payments using the proposed FY 2012 MS–LTC–DRGs and relative weights. Furthermore, consistent with our historical policy of using the best available data, we also are proposing that if more recent data become available, we would use such data to determine the budget neutrality adjustment factor for FY 2012 in the final rule.

For this proposed rule, we are proposing to determine the proposed FY 2012 budget neutrality adjustment factor using the following three steps: (2.a.) we simulated estimated total LTCH PPS payments using the proposed normalized relative weights for FY 2012 and proposed GROUPER Version 29.0 (as described above); (2.b.) we simulated estimated total LTCH PPS payments using the FY 2011 GROUPER (Version 28.0) and the FY 2011 MS–LTC–DRG relative weights shown in Table 11 of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50613 through 50626); and (2.c.) we calculated the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2011 GROUPER (Version 28.0) and the FY 2011 MS–LTC–DRG relative weights (determined in step 2.b.) by the estimated total LTCH PPS payments using the proposed FY 2012 GROUPER (Version 29.0) and the proposed normalized MS–LTC–DRG relative weights for FY 2012 (determined in Step 2.a.). In determining the proposed FY 2012 MS–LTC–DRG relative weights, each proposed normalized relative weight was multiplied by a budget neutrality factor of 0.994312 in the second step of the proposed budget neutrality methodology to determine the proposed budget neutral FY 2012 relative weight for each proposed MS–LTC–DRG.

Accordingly, in determining the proposed FY 2012 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.11482 and a budget neutrality factor of 0.994312 (computed as described above). Table 11, which is listed in sectin VI. of the Addendum to this proposed rule and is available via the Internet, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used in determining SSO payments under § 412.529) for FY 2012. The proposed FY 2012 MS–LTC–DRG relative weights in Table 11, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, reflect both the proposed normalization factor of 1.11482 and the proposed budget neutrality factor of 0.994312.

C. Proposed Quality Reporting Program for LTCHs

1. Background and Statutory Authority

CMS seeks to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by quality reporting programs coupled with public reporting of that information. Such quality reporting programs already exist for various settings such as hospital inpatient services via the Hospital Inpatient Quality Reporting (IQR) Program (formerly called the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program), hospital outpatient services via the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), and physicians' and other eligible professionals' services via the Physician Quality Reporting System (formerly called the Physician Quality Reporting Initiative, or PQRI). We have also implemented quality reporting programs for home health agencies and skilled nursing facilities that are based on conditions of participation, and an end-stage renal disease quality incentive program (ESRD QIP) that links payment to performance.

Section 3004(a) of the Affordable Care Act authorizes an additional quality reporting program for LTCHs, by adding a new paragraph (5) to section 1886(m) of the Act. Section 1886(m)(5)(A)(i) of the Act requires that, for rate year 2014 and each subsequent rate year, the Secretary shall reduce any annual update to the standard Federal rate for discharges occurring during such rate year, by 2 percentage points, for any LTCH that does not comply with quality data submission requirements with respect to an applicable rate year. We note that section 1886(m)(5) of the Act uses the term "rate year." Beginning with the annual update to the LTCH PPS that took effect on October 1, 2009, we consolidated the rulemaking cycle for the annual update of the LTCH PPS Federal payment rates with the annual update of the MS–LTC–DRG classifications and weights so that the annual updates to the rates and factors have an October 1 effective date and occur on the same schedule. To reflect this change to the annual payment rate update cycle, we revised the regulations at § 412.503 to specify that, beginning on or after October 1, 2009, the "LTCH PPS rate year" is defined as October 1 through September 30 (73 FR 26797 through 26798 and 26838). Beginning October 1, 2010, we changed from using the term "rate year" to "fiscal year" under the LTCH PPS in order to conform to the standard definition of the Federal fiscal year (October 1 through September 30). For LTCH PPS purposes, the term "rate year" and the term "fiscal year" both refer to the time period beginning October 1 and ending September 30. For more information regarding this terminology change, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50396 and 50397). For purposes of the discussion below, in order to eliminate any possible confusion that may be caused by using the term "rate year" with respect to the proposed Quality Measurement Reporting Program for LTCHs, we will use the term "fiscal year" rather than "rate year."

As provided at section 1886(m)(5)(A)(ii) of the Act, depending on the amount of annual update for a particular year, a reduction of 2.0 percentage points may result in the annual update being less than 0.0 percent for a fiscal year and may result in payment rates under the LTCH PPS being less than payment rates for the preceding fiscal year. In addition, as set forth at section 1886(m)(5)(B) of the Act, any reduction based on failure to comply with the reporting requirements, as required by section 1886(m)(5)(A) of the Act, shall apply only with respect to the particular fiscal year involved, and any such reduction shall not be taken into account in computing the payment rate for subsequent fiscal years.

Section 1886(m)(5)(C) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, each LTCH shall submit to the Secretary data on quality measures as specified by the Secretary. Such data must be submitted in a form and manner, and at a time, specified by the Secretary. Any measures selected by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act. This contract is currently held by the NQF. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process. We have generally adopted NQF-endorsed measures in our reporting programs.

However, section 1886(m)(5)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act (currently, NQF), the Secretary may specify a measure(s) that is (are) not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Under section 1886(m)(5)(D)(iii) of the Act, the Secretary shall publish, by no later than October 1, 2012, measures which shall be applicable with respect to the FY 2014 payment determination.

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making data submitted under the LTCH quality reporting program available to the public. The Secretary must ensure that each LTCH has the opportunity to review the data that are to be made public with respect to that facility prior to such data being made public. The Secretary must also report quality measures that relate to services furnished in LTCHs on the CMS Web site.

2. Proposed Quality Measures for the LTCH Quality Reporting Program for FY 2014

a. Considerations in the Selection of the Proposed Quality Measures

In implementing the LTCH quality reporting program, we believe that the development of a quality reporting program that is successful in promoting the delivery of high quality health care services in LTCHs is of paramount importance. As the statute provides in section 1886(m)(5)(D) of the Act, in establishing the LTCH quality reporting program, we must publish quality measures to be reported with respect to the FY 2014 payment determination no later than October 1, 2012. In an effort

to meet that mandate, we sought to develop a quality reporting program that incorporates overarching health care aims and goals intended to facilitate quality care in a manner that is effective and meaningful, while remaining mindful of reporting burden and feasibility of data collection by LTCHs, in order to reduce and avoid duplicative reporting efforts when possible. We seek to efficiently collect information on valid, reliable, and relevant measures of quality and to share this information with the public, as provided at section 1886(m)(5)(E) of the Act.

Several provisions of the Affordable Care Act, taken together, call on the Secretary to establish a national strategy to provide a comprehensive plan and priorities to improve the delivery of health care services, patient health outcomes, and population health through a transparent, collaborative process. This strategy, the National Quality Strategy, was released by the Secretary (available on the Web site at: *http://www.healthcare.gov/center/reports/quality03212011a.html#es)*. We have used the priorities of the National Quality Strategy to guide identification of the proposed quality measures for LTCHs under section 1886(m)(5) of the Act.

We also applied the following additional considerations and criteria in selecting the proposed quality measures for LTCHs: whether a measure is included in, or facilitates alignment with, other Medicare and Medicaid programs; whether a measure addresses HHS priorities, such as prevention, care of chronic illness, high prevalence conditions, patient safety, patient and caregiver engagement, and care coordination; and whether a measure is evidence-based and may drive quality improvement as well as has a low probability of causing unintended adverse consequences, such as reduced LTCH admissions of higher risk patients.

Furthermore, at the Listening Session held on November 15, 2010, for the Affordable Care Act section 3004 quality reporting programs, we sought input, and invited comments and suggestions, regarding quality reporting, quality measurement recommendation, prioritization, and feasibility, and did the same through the use of a Special Open Door Forum held on December 16, 2010, for the Affordable Care Act section 3004 quality reporting programs. Transcripts for both the Listening Session and the Open Door Forum can be found on the CMS Web site at: *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting.*

In addition, we invited suggestions and input regarding the section 3004 quality reporting programs to be sent to us using the CMS Web site mail box *LTCH-IRF-Hospice-Quality-ReportingComments@cms.hhs.gov* found at *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting.* We also received suggestions and input from a LTCH technical expert panel (TEP), convened by the CMS measure development contractor on January 31, 2011, that reviewed and prioritized the quality measures identified by a LTCH environmental scan led by a CMS measures development contractor, RTI International, specifically for the LTCH quality reporting program. Specifically, this TEP reviewed measures found in the environmental scan and rated them for importance, scientific soundness, usability, and feasibility.

In sum, in selecting the proposed quality measures discussed below, with applicability for FY 2014 and subsequent years, our goal is to achieve several objectives. First, the proposed measures should relate to the general aims of better care for the individual, better population health, and lower cost through better quality. Second, the proposed measures should promote improved quality specifically to the priorities that are of most relevance to LTCHs. These include patient safety, such as avoiding healthcare-associated infections (HAIs) and adverse events, better coordination of care, and person-centered and family-centered care. Third, the proposed measures should address improved quality for the primary role of LTCHs, which is to furnish extended medical care to individuals with clinically complex problems, such as multiple acute or chronic conditions, that need hospital-level care for relatively extended periods of greater than 25 days.

b. Proposed LTCH Quality Measures for FY 2014 Payment Determination

We are proposing that, for the FY 2014 payment determination, LTCHs submit data on three quality measures: (1) Urinary Catheter-Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Blood Stream Infection (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened

HAIs are a topic area widely acknowledged by the HHS Action Plan to Prevent HAIs, the Institute of Medicine (IOM), the National Priorities Partnership, and others as a high impact priority requiring measurement and improvement. Better care is one of the aims found in the National Quality Strategy, and patient safety is one of the priorities. Mitigating HAIs is essential in the improvement of patient safety, and, therefore, patient care. HAIs are among the leading causes of death in the United States and, therefore, are serious reportable events. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths per year.[50] HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs. Therefore, two of the three quality measures proposed are HAI measures.

Other HAIs included in the HHS Action Plan to Prevent HAIs were under consideration for the LTCH quality reporting program beginning October 1, 2012. However, the TEP convened by the measure development contractor recommended the two proposed infection events, urinary catheter-associated urinary tract infection and central line catheter-associated bloodstream infection (each an episode of an infection, such as CAUTI or CLABSI) as highly pertinent, and important for data collection as well as most ready and currently feasible for implementation in the LTCH setting. HAI quality measures are important for quality reporting, and we intend to propose additional HAI measures included in the HHS HAI Action Plan to Prevent HAIs through future rulemaking. These potential HAI quality measures are listed in our discussion of possible measures under consideration for future years. At this time, we are proposing the selection of the CLABSI and CAUTI events as the two initial HAI quality measures for the LTCH quality measure reporting program.

(1) Proposed FY 2014 LTCH Measure #1: Urinary Catheter-Associated Urinary Tract Infections (CAUTI)

The first measure we are proposing for LTCHs for purposes of the FY 2014 payment determination is an application of the NQF-endorsed measure developed by CDC for hospital intensive care units (ICU) entitled (NQF# CAUTI 0138) "Urinary Catheter-Associated Urinary Tract Infection [CAUTI] rate per 1,000 urinary catheter days, for Intensive Care Unit Patients" to all LTCH care units. This measure was developed by the CDC to measure the percentage of patients with CAUTIs in the ICU context. At the time we are developing this proposed rule, the measure we are applying, NQF CAUTI #0138, is undergoing measure

[50] McKibben L; Horan T: Guidance on public reporting of healthcare-associated infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005;33:217 through 226.

maintenance review by NQF. This review may result in a change in how the CDC calculates the aggregated data from using a rate for CAUTI, to the use of a Standardized Infection Ratio (SIR) of healthcare associated catheter-associated urinary tract infections. We are proposing to adopt the current measure in this rulemaking cycle. However, we intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking.

While it is fast becoming a medical best practice to avoid urinary catheter use whenever possible, this may not always be possible with the LTCH patient population, due to the severity of their primary illnesses as well as comorbidities. Patients who are exposed to indwelling urinary catheters have a significantly higher risk of developing urinary tract infections (UTIs).

UTIs are a common cause of morbidity and mortality. The HHS National Action Plan to Prevent HAIs identified catheter associated urinary tract infections as the leading type of HAI that is largely preventable, and the occurrence of which can be drastically reduced in order to reduce adverse health care related events and avoid excess costs.

The urinary tract is the most common site of HAI, accounting for more than 30 percent of infections reported by acute care hospitals.[51] Healthcare-associated UTIs are commonly attributed to catheterization of the urinary tract.

CAUTI can lead to such complications as cystitis, pyelonephritis, gram-negative bacteremia, prostatitis, epididymitis, and orchitis in males and, less commonly, endocarditis, vertebral osteomyelitis, septic arthritis, endophthalmitis, and meningitis in all patients. Complications associated with CAUTI also include discomfort to the patient, prolonged hospital stay, and increased cost and mortality. Each year, more than 13,000 deaths are associated with UTIs.[2] Prevention of CAUTIs is discussed in the CDC/HICPAC document, *Guideline for Prevention of Catheter-associated Urinary Tract Infections.*[52] The NQF-endorsed CAUTI measure we are proposing is currently collected by the National Healthcare Safety Network (NHSN) as part of State-mandated reporting and surveillance requirements for hospitals. We note that CDC's NHSN is a secure Internet-based surveillance system that currently has data collection forms and data submission and reporting mechanism in place for LTCHs. NHSN is currently used, in part, as one means by which certain State-mandated reporting and surveillance data are collected.

We recognize that the NQF has endorsed this measure for the short term, acute care ICU setting, but believe that this measure is highly relevant to LTCHs, in that urinary catheters are commonly used in the LTCH care setting. As previously noted, NQF CAUTI #0138 is undergoing measure maintenance review by NQF. This review may result in a change in how CDC calculates the aggregated data from using a rate for CAUTI to the use of a SIR). We are proposing to adopt the current measure in this rule making cycle. However, we intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking. The TEP convened by the CMS measure development contractor on January 31, 2011, identified CAUTI as a high priority quality issue for LTCHs, and there was agreement by this TEP that this particular infection rate is worthy of surveillance within LTCHs. This measure is applicable for surveillance in long-term care units (CDC/NHSN Manual, Device-Associated Module, CAUTI Event, which is available on the CDC Web site at: *http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTIcurrent.pdf.*

Section 1886(m)(5)(D)(ii) of the Act provides that "[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary." We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed measures for urinary catheter-associated urinary tract infections for the LTCH setting. We are unaware of any other measures for catheter-associated urinary tract infections that have been approved by a voluntary consensus standards bodies and endorsed by NQF. We are proposing to adopt an application of this NQF-endorsed (in the short-term acute care ICU setting) measure under the Secretary's authority to select non-NQF-endorsed measures. We are proposing to adopt the measure under the exception authority provided in section 1886(m)(5)(D)(ii) of the Act. As previously noted, NQF CAUTI #0138 is undergoing measure maintenance review by NQF. This review may result in changes to this measure's specifications in how CDC calculates the aggregated data from using a rate for CAUTI to the use of a SIR. We are proposing to adopt the current measure in this rulemaking cycle. We intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking. We note that we intend to ask NQF to formally extend its endorsement of the CAUTI measure to the LTCH setting.

(2) FY 2014 Measure #2: Central Line Catheter-Associated Bloodstream Infection (CLABSI)

The second measure we are proposing for LTCHs for the FY 2014 payment determination is an application of a CDC-developed NQF-endorsed measure for hospital ICU and high-risk nursery patients; (NQF# CLABSI 0139) "Central Line Catheter-Associated Bloodstream Infection (CLABSI) Rate for ICU and High-Risk Nursery (HRN) Patients." This is a measure of the percentage of ICU and high-risk nursery patients who, over a certain amount of days, acquired central line catheter-associated bloodstream infections over a specified number of line days. At the time we are developing this proposed rule, the measure we are proposing to apply, NQF CLABSI #0139, is undergoing measure maintenance review by NQF. This review may result in a change in how CDC calculates the aggregated data from using a rate for CLABSI to the use of a SIR of health care associated CLASBIs. We propose to adopt the measure in its current state in this rulemaking cycle. We intend to propose the adoption of any modifications to this measure that may result from the NQF review process in a future rule cycle.

A central line is a catheter that health care providers often place in a large vein in the neck, chest, or groin to give medication or fluids or to collect blood for medical tests. Many LTCH patients have been discharged from short-term acute care hospital ICUs or ICU step-down units with these central lines already in place. In other situations, a central line IV may be inserted during the patient's stay at the LTCH. Bloodstream infections are usually serious infections typically causing a prolongation of hospital stay and

[51] Klevens RM, Edward JR, *et al.* Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160–166.

[52] Wong ES. Guideline for prevention of catheter-associated urinary tract infections. Infect Control 1981;2:126–30.

increased cost and risk of mortality.[53] An estimated 248,000 bloodstream infections occur in U.S. hospitals each year.[54] Furthermore, CLABSIs result in thousands of deaths each year and billions of dollars in added costs to the U.S. healthcare system, yet these infections are preventable. The CDC is providing guidelines and tools to the health care community to help reduce central line catheter-associated bloodstream infections. Techniques to prevent CLABSI through proper central line management are addressed in CDC's Healthcare Infection Control Practices Advisory Committee Guidelines for the Prevention of Intravascular Catheter Related Infections.[55]

We recognize that NQF endorsement of this measure is limited to ICU and HRN patients in hospital settings, but believe that this measure is also highly relevant in the LTCH setting because intravascular, central venous catheters (also known as a "central line") are used frequently due to the fact that these types of hospitals care for patients with complex medical problems which require LTCH stays and intensive treatment. As previously noted, NQF CLABSI #0139 is undergoing measure maintenance review by NQF. This review may result in changes to this measure's specifications in how CDC calculates the aggregated data from using a rate for CLABSI to the use of a SIR. We are proposing to adopt the current measure in this rulemaking cycle. We intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking. The CMS measure development contractor convened a TEP on January 31, 2011, which identified CLASBIs as a high priority quality issue for LTCHs; there was agreement by the TEP that this particular infection rate is worthy of surveillance within LTCHs. This measure is applicable for surveillance in long-term hospital care units (CDC/NHSN Manual, Device-Associated Module, CLABSI Event, which is available at the CDC Web site at: *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.*

Section 1886(m)(5)(D)(ii) of the Act provides that "[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary." We reviewed the NQF's consensus-endorsed measures, and were unable to identify any NQF endorsed measures for central line catheter-associated bloodstream infections for the LTCH setting. We are unaware of any other measures for CLABSI that have been approved by voluntary consensus standards bodies and endorsed by NQF. Therefore, we are proposing to adopt an application of this NQF-endorsed (for ICU and HRN) measure under the Secretary's authority provided in section 1886(m)(5)(D)(ii) of the Act. As previously noted, NQF CLABSI #0139 is undergoing measure maintenance review by NQF. This review may result in changes to this measure's specifications in how CDC calculates the aggregated data from using a rate for CLABSI to the use of a SIR. We are proposing to adopt the measure in its current state in this rulemaking cycle. We intend to propose the adoption of any modifications to this measure that may result from the NQF review process in future rulemaking. We note that we intend to ask NQF to formally extend its endorsement of the CLABSI measure to all care settings within the LTCH (that is, beyond the LTCH ICU).

(3) FY 2014 Measure #3: Pressure Ulcers

The third measure we are proposing for LTCHs for purposes of the FY 2014 payment determination is an application of a CMS-developed NQF-endorsed measure for short-stay nursing home patients: (NQF NH–012–10) "Percent of Residents with Pressure Ulcers that Are New or Have Worsened." This measure includes the percentage of patients who have one or more stage 2–4 pressure ulcers that are new or worsened from a previous assessment. Consistent in our support of the National Quality Strategy principles, mitigating the occurrence or worsening of pressure ulcers is essential in the improvement of patient safety and, therefore, patient care.

We recognize NQF endorsement of this measure is limited to short-stay nursing home patients, but believe that this measure is highly relevant and a high priority quality issue for the care of LTCH patients. Pressure ulcers are high-volume and high-cost adverse events across the spectrum of health care settings from acute hospitals to home health. Patients in the LTCH setting are medically complex, have functional limitations that often are severe, and, therefore, are at high risk for the development, or worsening, of pressure ulcers. Pressure ulcers are serious medical conditions and an important measure of quality. Pressure ulcers can lead to serious, life-threatening infections, which substantially increase the total cost of care. Furthermore, as we noted in the FY 2008 IPPS final rule with comment period (72 FR 42705), in 2006 there were 322,946 reported cases of Medicare patients with a pressure ulcer as a secondary diagnosis—each case had an average charge of $40,381 for a hospital stay, for an annual total cost of 13 billion dollars. The prevalence of pressure ulcers in health care facilities is increasing, with some 2.5 million patients being treated annually for pressure ulcers in acute care facilities.[56] [57] In 2006, there were 503,300 acute hospital stays during which pressure ulcers were noted. This is a 78.9 percent increase from 1993 when there were about 281,300 hospital stays related to pressure ulcers.[58]

The CMS measure development contractor convened a TEP on January 31, 2011, which identified this topic as highly relevant and a high priority quality issue for the care of LTCH patients, and the application of this measure (NQF NH–012–10) as appropriate for LTCHs.

Section 1886(m)(5)(D)(ii) of the Act provides that "[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary." We

[53] CDC/NHSN Manual. Device-Associated Module, CLABSI Event. Available at *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf,* assessed on Jauary 20, 2011.

[54] Klevens RM, Edward JR, *et al.* Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160–166.

[55] O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, *et al.* Guidelines for the prevention of intravascular catheter-related infections. MMWR 2002;51(No. RR–10:1–26.

[56] Russo CA, Steiner C, Spector W.: *Hospitalizations related to pressure ulcers among adults 18 years and older, 2006* (Healthcare Cost and Utilization Project Statistical Brief No. 64). December 2008. Available at: *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb64.pdf.*

[57] Institute for Healthcare Improvement: Relieve the pressure and reduce harm. May 21, 2007. Available at: *http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/ImprovementStories/FSRelievethePressureandReduceHarm.htm.*

[58] MacLean DS.: Preventing & managing pressure sores. Caring for the Ages. March 2003;4(3):34–7. Available at: *http://www.amda.com/publications/caring/march2003/policies.cfm.*

reviewed the NQFconsensus-endorsed measures, and we were unable to identify any NQF-endorsed measures for the monitoring of pressure ulcers that are new or worsened, for the LTCH setting. We are unaware of any other measure for the LTCH setting of new or worsened pressure ulcers that are approved by voluntary consensus standards bodies and endorsed by NQF. Therefore, we are proposing to adopt an application of this NQF-endorsed (for short-stay nursing home patients) measure for the LTCH quality reporting program under the Secretary's authority set forth at section 1886(m)(5)(D)(ii) of the Act. We also intend to ask NQF to extend its endorsement of the short-stay nursing home pressure ulcer measure specifically to the LTCH setting.

We invite public comment on the proposed quality measures: (1) Urinary Catheter Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Bloodstream Infection (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened.

3. Possible LTCH Quality Measures Under Consideration for Future Years

As discussed below, we seek to achieve a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement. Therefore, as stated previously, we intend to propose, through future rulemaking, measures included in the HHS Action Plan to Prevent HAIs. We also intend to propose through future rulemaking measures related to ventilator care such as the NQF-endorsed Institute for Healthcare Improvement process measure, NQF #0302, Ventilator Bundle, which is a comprehensive ventilator care-bundle process measure that is designed to facilitate protocols such as weaning, and mitigate ventilator-related infections, such as ventilator-associated pneumonia, and other complications. We also intend to propose additional outcome measures such as those related to acute care rehospitalization. We are aware of the limits related to feasibility in data submission at the present time. For example, there is no feasible means to submit the ventilator bundle process measure at this at this time, and are therefore currently identifying the data elements necessary for this measure using a data subset from the Continuity Assessment Record and Evaluation (CARE) data set as well as a submission mechanism. We also intend to propose, through future rulemaking, additional measures, such as those related to symptom management, physical restraints, medication use, falls, infections, and function, using the data subsets of the CARE data set necessary for measure calculations. We invite public comment and suggestions on the implementation of a standardized assessment instrument for LTCHs that would similarly support the calculation of quality measures. We also invite public comment on the measures and measures topics under consideration for future years set out below. In addition, we invite other suggestions and rationale to support the adoption of measures and topics not listed below.

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Possible Measures and Measure Topics for the LTCH Quality Reporting Program Under Consideration for Future Years	
Overarching Goal: Safety and Healthcare Acquired Conditions -- HAIs	
	HAI reporting for: ● Ventilator-associated Pneumonia*** ● Surgical site infection rate*** ● Multi-drug resistant organism infection
Overarching Goal: Safety and Healthcare Acquired Conditions: Avoidable Adverse Events and Serious Reportable Events	
	● Unplanned acute care hospitalizations ● Mortality*** ● Blood Incompatibility** ● Foreign object retained after surgery** ● Manifestation of poor glycemic control** ● Air Embolism** ● Falls and trauma** ● Venous Thromboembolism* ● Injuries secondary to Poly-pharmacy ● Injuries related restraint use ● Medication errors* ● Stage III and IV Pressure Ulcer**
Overarching Goal: Safety and Improvement Practices for Adverse Event Reduction	
	● Central line bundle*** ● Ventilator bundle*** ● Patient Immunization for Influenza*** ● Patient Immunization for Pneumonia*** ● Staff immunization***
Overarching Goal: Safety -- NQF Endorsed Nursing Sensitive Care Measures	
	● Patient Fall Rate*** ● Falls with Injury*** ● Pressure Ulcer Prevalence*** ● Restraint Prevalence (vest and limb only)*** ● Skill mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract)***Nursing care hours per patient day (RN, LPN, UAP)*** ● Voluntary turnover for RN, APN, LPN, UAP*** ● Practice Environment Scale-Nursing Work Index***

*Harmonizes with NQF Serious Reportable Events.
**Harmonizes with Hospital-Acquired Conditions –Present on Admission Program for IPPS hospitals.
***Harmonizes with NQF-endorsed measures.

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4. Proposed Data Submission Methods and Timelines

a. Proposed Method of Data Submission for HAIs

We are proposing to adopt two proposed HAI quality measures, Central Line Catheter-Associated Blood Stream Infection (CLABSI) Event: CLABSI rate per 1000 central line days, and Urinary Catheter-Associated Urinary Tract Infection (CAUTI) Event: CAUTI rate per 1000 urinary catheter days. We are proposing to use CDC/NHSN for data collection and reporting for these two HAI measures (*http://www.cdc.gov/nhsn/*).

As we noted above, the NHSN is a secure, Internet-based surveillance system. It is maintained by CDC, and can be utilized by all types of healthcare facilities in the United States, including LTCHs, acute care hospitals that collect and report HAIs through the NHSN as part of our Hospital IQR Program, as well as psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, and ambulatory surgery centers. The NHSN enables health care facilities to submit their HAI event data, and access their data for the purposes of internal infection-surveillance.

Facilities can also use the NHSN to obtain information on clinical practices known to prevent HAIs, information on the incidence or prevalence of multidrug-resistant organisms within their organizations, and information on other adverse events. Some States use the NHSN as a means of collecting State law-mandated HAI reporting. NHSN collects data via a Web-based tool hosted by the CDC and available at: *http://www.cdc.nhsn.* This reporting service is provided free of charge to healthcare facilities. In addition, CDC may have the ability to receive NHSN measures data from electronic health records (EHRs) in the near future. Currently, the data reporting of these two HAI events is completed through the NHSN. More than 20 States require hospitals to report HAIs using NHSN, and CDC supports more than 4,000 hospitals that are using the NHSN. Over 80 LTCHs currently submit HAI data via the NHSN.

HAI event reporting, and meaningful HAI event surveillance by the LTCH, using the CDC/NHSN requires the submission of HAI events, regardless of payor. We believe delivery of high quality care in the LTCH setting is imperative. Collecting such quality data on all patients in the LTCH setting supports CMS' mission to ensure high quality care for Medicare beneficiaries. This will provide us with the most robust and accurate reflection of quality in the LTCH setting. Therefore, in order to facilitate and ensure that high quality care is delivered to Medicare beneficiaries in the LTCH setting, we are proposing that quality data related to HAIs be collected on all LTCH patients, regardless of payor.

Currently the NHSN has data collection forms and data submission and reporting mechanisms in place that are in use by LTCHs for these CLABSI and CAUTI measures. Details related to the procedures using the NHSN for data submission can be found at: *http://www.cdc.gov/nhsn.* Specifically, details related to the procedures of using the NHSN for data submission and information on definitions, numerator data, denominator data and data analyses for CLABSI Event: CLABSI rate per 1000 central line days calculated by dividing the number of CLABSI by the number of central line days and multiplying the result by 1000 can be found at *http://www.cdc.gov/nhsn/PatientSafety.html.* Details related to the CLABSI SIR can be found at *http://www.cdc.gov/hai/pdfs/stateplans/SIR_05_25_2010.pdf.* Details related to the procedures of using the NHSN for data submission and information on definitions, numerator data, denominator data and data analyses for CAUTI Event: CAUTI rate per 1000 urinary catheter days calculated by dividing the number of CAUTIs by the number of catheter days and multiplying the result by 1000 can also be found at *http://www.cdc.gov/nhsn/PatientSafety.html.*

The reporting procedures for these HAI events would not be affected by the use of the SIR instead of the current rate calculation. CDC performs those calculations. Further information related to the use of the SIRs can be found on the Web sites at: *http://www.hhs.gov/ash/initiatives/hai/appendices.html* and *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html.*

b. Proposed Timeline for Data Reporting Related to HAIs

CDC recommends that HAI reporting occur closest in time to the event, and further recommends that reporting occur no later than 30 days following the event. To facilitate HAI surveillance and reporting for these proposed measures for payment determination, we are proposing an additional timeframe for reporting following the initial reporting period. We are proposing a data submission timeframe for NHSN event reporting for these proposed LTCH quality reporting program HAI measures of October 1, 2012 through December 31, 2012 for the determination of FY 2014 annual payment update, and that LTCHs submit their data no later than May 15, 2013.

In order to better align with the current Hospital IQR Program HAI reporting processes (75 FR 20223), we also are proposing that all subsequent LTCH quality reporting cycles will be based on a calendar year cycle (for example, beginning January 1, 2013 through December 31, 2013) for determination of the update to the standard Federal rate for each LTCH in FY 2015 and subsequent years. We are proposing that, beginning in CY 2013, and for all subsequent years, LTCHs would submit HAI event data via the NHSN, for four consecutive quarters of the calendar year. For example, for the FY 2015 annual payment update to the standard Federal rate, LTCHs would submit HAI data collected in the first quarter of CY 2013, the second quarter of CY 2013, the third quarter of CY 2013, and the fourth quarter of CY 2013.

The proposed timelines for submission of quality data on the CLABSIs and CAUTIs for the FY 2015 annual payment update are set out below.

Proposed Timelines for Submission of Data on the Proposed Central Line Catheter-Associated Bloodstream Infections and Urinary Catheter-Associated Urinary Tract Infections (CAUTI & CLABSI) Measures for the FY 2015 Annual Payment Update		
CY 2013 Infection Event (s)	**CDC-NHSN collection and quarterly report generation time**	**Proposed final submission deadlines for the LTCH quality reporting program FY 2015 payment determination**
Q1 (January-March 2013)	January 31-August 15	August 15, 2013
Q2 (April-June 2013)	April 30-November 15	November 15, 2013
Q3 (July-September 2013)	July 31-February 15	February 15, 2014
Q4 (October-December 2013)	October 31-May 15	May 15, 2014

LTCHs would have until the final submission deadline for the LTCH quality reporting program to submit their quarterly data to the NHSN. After the final submission deadline has occurred for each CY 2013 quarter, CMS will receive a file from the CDC with the aggregated measurement rates of the specific calculations that have been generated by the NHSN for the LTCH quality reporting program and we will use those results for purposes of determining whether the LTCH met the requirements for the LTCH quality reporting program. We invite public comments on the proposed reporting cycle for LTCHs.

In alignment with the Hospital IQR Program, (75 FR 50223), we also are proposing that once quarterly each LTCH will utilize an automated report function that will be made available to submitters in the NHSN, to generate a quarterly report containing individual LTCH-level numerator, denominator, and exclusion counts for these two HAI measures specifically. CDC will create an automated LTCH quality program report function and add it to NHSN's reporting functionalities. While LTCHs may be reporting other data elements to CDC for other reporting programs (that is: State-mandated surveillance programs), the quarterly LTCH quality program report that would be generated within NHSN would only contain those data elements needed to calculate the two measures currently being proposed for the LTCH quality reporting program. We would only receive this aggregated data from CDC.

We also are proposing that any further details regarding data submission and reporting requirements for HAI measures to be reported via NHSN would be posted on the CMS Web site at: *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/* by no later than January 31, 2012.

Requirements for NHSN participation, measure specifications, and data collection can be found at the Web site at: *http://www.cdc.gov/nhsn/*. LTCHs are encouraged to visit this Web site in order to view the NHSN enrollment and reporting requirements. Training resources are available there. In order to allow adequate time for enrollment in the NHSN, and for training to take place, should these measures be finalized, additional details related to this reporting program's requirements, such as when enrollment is due to occur, will be announced by no later than January 31, 2012, on the CMS Web site at: *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/*. In the announcement, we would propose to provide guidance on the specifications, definitions and reporting requirements.

We invite public comments on the proposed HAI NHSN submission requirements, reporting cycle, and reporting timeline for LTCHs.

c. Proposed Method of Data Collection and Submission for the Pressure Ulcer Measure Data

We are proposing that the pressure ulcer data elements necessary to calculate the pressure ulcer measure would be identical to those data elements collected through the Minimum Data Set 3.0 (MDS 3.0), which is a reporting instrument used in nursing homes The current MDS 3.0 pressure ulcer items evolved as an outgrowth of CMS' work to develop a standardized patient assessment instrument, referred to as the Continuity Assessment Record and Evaluation tool, or CARE. The current MDS 3.0 pressure ulcer items are also currently used in the calculation of the NQF-endorsed nursing home pressure ulcer measure, Percent of Residents With Pressure Ulcers That Are New or Worsened [Short Stay] (NQF NH–012–10). We note that the MDS data elements were supported by the National Pressure Ulcer Advisory Panel (NPUAP).

We believe that to support the standardized collection and calculation of the LTCH pressure ulcer quality measure will require the use of a subset of the standardized CARE instrument, and thus we are proposing the use of a subset of the CARE instrument's assessment items for data collection. We will be using specifically the pressure ulcer data elements necessary to calculate the pressure ulcer measure, and those data items are identical to those data elements collected through the Minimum Data Set 3.0 (MDS 3.0). The current MDS 3.0 pressure ulcer data items can be found at the CMS Web site at: *https://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp.*[59] This data assessment subset will allow identical data elements to be collected in LTCHs and in nursing homes.

The CARE assessment instrument, was developed and tested in the post-acute care payment reform demonstration (which included LTCHs) as required by section 5008 of the Deficit Reduction Act (DRA) (Pub. L. 109–171). It is a standardized assessment instrument that can be used across all postacute care sites to measure functional status and other factors during treatment and at discharge from each provider. (For more information, we refer readers to the following Web site: *http://www.pacdemo.rti.org.*) CARE was tested

[59] *https://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp* (Look for Downloads. Select MDS 3.0 Item Subsets v1.002. Click on MDS 3.0 ALL Items. Scroll down to Section M, Skin Conditions, items M0100–M0900.)

over the last 2 years in 199 providers, of which 28 were LTCHs. Participant feedback suggested most of these items are already collected by LTCHs during their intake process and in monitoring the patients' health status during the stay. Importantly, the CARE items meet Federal interoperable data standards and should be transferable by most data systems. A data collection mechanism for transferring the data to CMS is currently under development, and it is anticipated to be similar to the current systems used to report assessment data for payment and quality monitoring in the other post acute care sites.

We believe that, for the collection of data necessary to calculate this pressure ulcer measure, using a CARE subset of standardized data elements to collect, report, and calculate the proposed pressure ulcer quality measure will drive uniformity across settings which will lead to better quality of care in LTCHs and, ultimately, across the continuum of care settings. We also believe that the use of a standardized method of communication will lead to better informed decision making.

If this proposal is finalized, additional details regarding the data elements needed to calculate this measure, submission requirements and specifications used for these data elements to calculate the proposed pressure ulcer quality measure using a subset of CARE instrument will be published on the CMS Web site at *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/* by no later than January 31, 2012.

We are proposing to use standardized assessment data elements for data collection that would support the calculation of quality measures in the LTCHs. Specifically, we are proposing to use a subset of the CARE instrument for the collection of the data elements necessary to calculate the proposed quality measure, the Percent of New or Worsened Pressure Ulcers.

We invite public comment on the use of a subset of CARE items for the purposes of data collection for this proposed measure: Percent of Patients with New or Worsened Pressure Ulcers. We invite public comment on this proposal for the calculation of the proposed quality measure for pressure ulcers.

d. Proposed Timeline for Data Reporting Related to Pressure Ulcers

The delivery of high quality care in the LTCH setting is imperative. We believe that collecting quality data on all patients in the LTCH setting supports CMS' mission to ensure quality care for Medicare beneficiaries. Collecting data on all patients provides the most robust and accurate reflection of quality in the LTCH setting. Accurate representation of quality provided in LTCHs is best conveyed using data related to pressure ulcers on all LTCH patients, regardless of payor. Thus, so as to facilitate and ensure this effort, we are proposing that quality data related to pressure ulcers shall be collected on all LTCH patients, regardless of payor, using a subset of the CARE data collection instrument in accordance with the timetable and schedule set forth in section VII.C.4.b. of this preamble. We will provide further details about the data collection instrument on the CMS Web site *http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/* as these details become available. We invite public comments on the proposed reporting cycle for LTCHs.

5. Public Reporting and Availability of Data Submitted

Under section 1886(m)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by LTCHs available to the public. Such procedures will ensure that a LTCH has the opportunity to review the data that is to be made public with respect to the LTCH prior to such data being made public. The Secretary will report quality measures that relate to services furnished in LTCHs on the CMS Web site. Currently, the agency is developing plans regarding the implementation of this provision. Procedures for public reporting will be proposed through future rule making. At this time no procedures or timeline has been established for public reporting of data.

D. Proposed Rebasing and Revising of the Market Basket Used Under the LTCH PPS

1. Background

The input price index (that is, the market basket) that was used to develop the LTCH PPS for FY 2003 was the "excluded hospital with capital" market basket. That market basket was based on 1997 Medicare cost report data and included data for Medicare-participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals. Although the term "market basket" technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term "market basket," as used in this section, refers to an input price index.

Beginning with RY 2007, LTCH PPS payments were updated using a FY 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). We excluded cancer and children's hospitals from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at § 413.40. They are not paid under a PPS. Also, the FY 2002 cost structures for cancer and children's hospitals are noticeably different than the cost structures of the freestanding IRFs, freestanding IPFs, and LTCHs. A complete discussion of the FY 2002-based RPL market basket appears in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 21062), we expressed our interest in exploring the possibility of creating a stand-alone LTCH market basket that reflects the cost structures of only LTCH providers. However, as we discussed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43967 through 43968), we are conducting further research to assist us in understanding the reasons for the variations in costs and cost structure between freestanding IRFs and hospital-based IRFs. We also are researching the reasons for similar variations in costs and cost structure between freestanding IPFs and hospital-based IPFs. We remain unable to sufficiently understand the observed differences in costs and cost structures between hospital-based IRFs and freestanding IRFs and between hospital-based IPFs and freestanding IPFs. Therefore, we do not believe it is appropriate at this time to propose stand-alone market baskets for IRFs, IPFs, and LTCHs.

We are currently exploring the viability of creating two separate market baskets from the current RPL market basket: One market basket would include freestanding IRFs and freestanding IPFs and would be used to update payments under both the IPF and IRF payment systems. The other market basket would be a stand-alone LTCH market basket. Depending on the outcome of our research, we may propose a stand-alone LTCH market basket in the next LTCH PPS update cycle. We invite public comment on the possibility of using this type of market basket to update LTCH payments in the future.

Under the LTCH PPS for FY 2012, we are proposing to rebase and revise the

FY 2002-based RPL market basket by creating a proposed FY 2008-based RPL market basket as described below. In the following discussion, we provide an overview of the market basket and describe the methodologies we are proposing to use for purposes of determining the operating and capital portions of the proposed FY 2008-based RPL market basket.

2. Overview of the Proposed FY 2008–Based RPL Market Basket

The proposed FY 2008-based RPL market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, we are proposing to use FY 2008 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called cost or expenditure weights. Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods.

3. Proposed Rebasing and Revising of the RPL Market Basket

We are inviting public comments on our proposed methodological changes to the RPL market basket. The terms "rebasing" and "revising," while often used interchangeably, actually denote different activities. "Rebasing" means moving the base year for the structure of costs of an input price index (for example, in this proposed rule, we are proposing to shift the base year cost structure for the RPL market basket from FY 2002 to FY 2008). "Revising" means changing data sources, price proxies, or methods, used to derive the input price index. For FY 2012, we are proposing to rebase and revise the market basket used to update the LTCH PPS.

a. Development of Cost Categories

(1) Medicare Cost Reports

The proposed FY 2008-based RPL market basket consists of several major cost categories derived from the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs, including wages and salaries, pharmaceuticals, professional liability insurance, capital, and a residual. These FY 2008 Medicare cost reports include providers whose cost report begin date is on or between October 1, 2007, and September 30, 2008. We are proposing to use FY 2008 as the base year because we believe that the Medicare cost reports for this year represent the most recent, complete set of Medicare cost report data available for IRFs, IPFs, and LTCHs. However, there is an issue with obtaining data specifically for benefits and contract labor from this set of FY 2008 Medicare cost reports because IRFs, IPFs, and LTCHs were not required to complete the Medicare cost report worksheet from which these data were collected (Worksheet S–3, Part II). As a result, only a small number of providers (less than 30 percent) reported data for these categories, and we do not expect these FY 2008 data to improve over time. However, because IRFs, IPFs, and LTCHs were not required to submit data for Worksheet S–3, Part II in previous cost reporting years, we have always had this issue of incomplete Medicare cost report data for benefits and contract labor (including when we finalized the FY 2002-based RPL market basket). Due to the incomplete benefits and contract labor data for IRFs, IPFs, and LTCHs, we are proposing to develop these cost weights using FY 2008 Medicare cost report data for IPPS hospitals (similar to the method that was used for the FY 2002-based RPL market basket). We provide additional detail on this approach later in this section.

Because our goal is to measure cost shares that are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries, we are proposing to limit our selection of Medicare cost reports to those from hospitals that have a Medicare average length of stay that is within a comparable range of their total facility average length of stay. We believe this provides a more accurate reflection of the structure of costs for Medicare covered days. We are proposing to use the cost reports of LTCHs and IRFs with Medicare average lengths of stay within 15 percent (that is, 15 percent higher or lower) of the total facility average length of stay for the hospital. This is the same edit we applied to derive the FY 2002-based RPL market basket and generally includes those LTCHs and IRFs with Medicare average length of stay within approximately 5 days of the facility average length of stay of the hospital.

We are proposing to use a less stringent measure of Medicare average length of stay for IPFs. For this provider type, and in order to produce a robust sample size, we are proposing to use those facilities' Medicare cost reports whose average length of stay is within 30 or 50 percent (depending on the total facility average length of stay) of the total facility average length of stay. This is the same edit we applied to derive the FY 2002-based RPL market basket.

We applied these length of stay edits to first obtain a set of cost reports for facilities that have a Medicare length of stay within a comparable range of their total facility length of stay. Using this set of Medicare cost reports, we then calculated cost weights for four cost categories and a residual as represented by all other costs directly from the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs (found in Table VII.D–1 below). These Medicare cost report cost weights were then supplemented with information obtained from other data sources (explained in more detail

below) to derive the proposed FY 2008-based RPL market basket cost weights.

TABLE VII.D-1.--MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED DIRECTLY FROM FY 2008 MEDICARE COST REPORTS

Major Cost Categories	Proposed FY 2008-Based RPL Market Basket (Percent)
Wages and Salaries	47.371
Professional Liability Insurance (Malpractice)	0.764
Pharmaceuticals	6.514
Capital	8.392
All other	36.959

(2) Other Data Sources

In addition to the IRF, IPF and LTCH Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs, the other data sources we used to develop the proposed FY 2008-based RPL market basket cost weights were the FY 2008 IPPS Medicare cost reports and the 2002 Benchmark Input-Output (I–O) Tables created by the Bureau of Economic Analysis (BEA), U.S. Department of Commerce. The FY 2008 Medicare cost reports include providers whose cost report begin date is on or between October 1, 2007, and September 30, 2008.

As noted above, the proposed FY 2008-based RPL cost weights for benefits and contract labor were derived using FY 2008-based IPPS Medicare cost reports. We used these Medicare cost reports to calculate cost weights for "wages and salaries," "benefits," and "contract labor" for IPPS hospitals for FY 2008. For the proposed benefits cost weight for the FY 2008-based RPL market basket, the ratio of the FY 2008 IPPS benefits cost weight to the FY 2008 IPPS wages and salaries cost weight was applied to the RPL wages and salaries cost weight. Similarly, the ratio of the FY 2008 IPPS contract labor cost weight to the FY 2008 IPPS wages and salaries cost weight was applied to the RPL wages and salaries cost weight to derive a contract labor cost weight for the proposed FY 2008-based RPL market basket.

The "All other" cost category is divided into other hospital expenditure category shares using the 2002 BEA Benchmark I–O data following the removal of the portions of the "all other" cost category provided in Table VII.D–1 that are attributable to the benefits and contract labor cost categories. The BEA Benchmark I–O data are generally scheduled for publication every 5 years. The most recent data available are for 2002. BEA also produces Annual I–O estimates; however, the 2002 Benchmark I–O data represent a much more comprehensive and complete set of data that are derived from the 2002 Economic Census. For the FY 2002-based RPL market basket, we used the 1997 Benchmark I–O data. We are proposing to use the 2002 Benchmark I–O data in the FY 2008-based RPL market basket. Instead of using the less detailed Annual I–O data, we aged the 2002 Benchmark I–O data forward to 2008. The methodology we used to age the data forward involves applying the annual price changes from the respective price proxies to the appropriate cost categories. We repeat this practice for each year.

The "all other" cost category expenditure shares are determined as being equal to each category's proportion to total "all other" expenditures based on the aged 2002 Benchmark I–O data. For instance, if the cost for telephone services represented 10 percent of the sum of the "all other" Benchmark I–O hospital expenditures, then telephone services would represent 10 percent of the "all other" cost category of the RPL market basket.

b. Final Cost Category Computation

As stated previously, for this FY 2012 rebasing proposal, we are proposing to use the Medicare cost reports for IRFs, IPFs, and LTCHs to derive four major cost categories. The proposed FY 2008-based RPL market basket includes two additional cost categories that were not broken out separately in the FY 2002-based RPL market basket: "Administrative and Business Support Services" and "Financial Services." The inclusion of these two additional cost categories, which are derived using the Benchmark I–O data, is consistent with the addition of these two cost categories to the FY 2006-based IPPS market basket (74 FR 43845). We are proposing to break out both categories so we can better match their respective expenses with more appropriate price proxies. A thorough discussion of our rationale for each of these cost categories is provided below in section VII.D.3.f. of this proposed rule. Also, the proposed FY 2008-based RPL market basket excludes one cost category: "Photographic Supplies." The 2002 Benchmark I–O weight for this category is considerably smaller than the 1997 Benchmark I–O weight, presently accounting for less than one-tenth of one percentage point of the RPL market basket. Therefore, we are proposing to include the photographic supplies costs in the "Chemicals" cost category weight with other similar chemical products.

We are not proposing to change our definition of the labor-related share. However, we are proposing to rename our aggregate cost categories from "labor-intensive" and "nonlabor-intensive" services to "labor-related" and "nonlabor-related" services. This is consistent with the FY 2006-based IPPS market basket (74 FR 43845). As discussed in more detail below and similar to the FY 2002-based RPL market basket, we classify a cost category as labor-related and include it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market. In previous regulations, we grouped cost categories that met both of these criteria into labor-intensive services. We believe the

proposed new labels more accurately reflect the concepts that they are intended to convey. We are not proposing to change our definition of the labor-related share because we continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

c. Selection of Price Proxies

After computing the FY 2008 cost weights for the proposed rebased RPL market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for Professional Liability Insurance, all of the proxies for the operating portion of the proposed FY 2008-based RPL market basket are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

Producer Price Indexes—Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that hospitals purchase as inputs because these PPIs better reflect the actual price changes encountered by hospitals. For example, we use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because hospitals generally purchase drugs directly from a wholesaler. The PPIs that we use measure price changes at the final stage of production.

Consumer Price Indexes—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price encountered by a producer, we used CPIs only if an appropriate PPI was not available, or if the expenditures were more similar to those faced by retail consumers in general rather than by purchasers of goods at the wholesale level. For example, the CPI for food purchased away from home is used as a proxy for contracted food services.

Employment Cost Indexes—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The proposed PPIs, CPIs, and ECIs selected meet these criteria.

Table VII.D–2 below sets forth the proposed FY 2008-based RPL market basket, including cost categories and their respective weights and price proxies. For comparison purposes, the corresponding FY 2002-based RPL market basket cost weights also are listed. For example, "Wages and Salaries" are 49.447 percent of total costs in the proposed FY 2008-based RPL market basket compared to 52.895 percent for the FY 2002-based RPL market basket. "Employee Benefits" are 12.831 percent in the proposed FY 2008-based RPL market basket compared to 12.982 percent for the FY 2002-based RPL market basket. As a result, compensation costs (wages and salaries plus employee benefits) for the proposed FY 2008-based RPL market basket are 62.278 percent of total costs compared to 65.877 percent for the FY 2002-based RPL market basket.

Following Table VII.D–2 is a summary outlining the choice of the proxies we are proposing to use for the operating portion of the FY 2008-based RPL market basket. The price proxies proposed for the capital portion are described in more detail in the capital methodology section below in section VII.D.3.d. of this proposed rule.

We note that the proxies for the operating portion of the FY 2008-based RPL market basket are the same as those used for the FY 2006-based IPPS operating market basket. Because these proxies meet our criteria of reliability, timeliness, availability, and relevance, we believe they are the best measures of price changes for the cost categories. For further discussion on the FY 2006-based IPPS market basket, we refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43843).

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TABLE VII.D-2.--PROPOSED FY 2008-BASED RPL MARKET BASKET COST CATEGORIES, WEIGHTS, AND PRICE PROXIES WITH FY 2002-BASED RPL MARKET BASKET COST WEIGHTS INCLUDED FOR COMPARISON

Cost Categories	FY 2002-Based RPL Market Basket Cost Weights	Proposed FY 2008-Based RPL Market Basket Cost Weights	Proposed FY 2008-Based RPL Market Basket Price Proxies
1. Compensation	65.877	62.278	--
A. Wages and Salaries[1]	52.895	49.447	ECI for Wages and Salaries, Civilian Hospital Workers
B. Employee Benefits[1]	12.982	12.831	ECI for Benefits, Civilian Hospital Workers
2. Utilities	0.656	1.578	--
A. Electricity	0.351	1.125	PPI for Commercial Electric Power
B. Fuel, Oil, and Gasoline	0.108	0.371	PPI for Petroleum Refineries
C. Water and Sewage	0.197	0.082	CPI-U for Water and Sewerage Maintenance
3. Professional Liability Insurance	1.161	0.764	CMS Hospital Professional Liability Insurance Premium Index
4. All Other Products and Services	22.158	26.988	--
A. All Other Products	13.325	15.574	--
(1.) Pharmaceuticals	5.103	6.514	PPI for Pharmaceutical Preparations for Human Use(Prescriptions)
(2.) Food: Direct Purchases	0.873	2.959	PPI for Processed Foods and Feeds
(3.) Food: Contract Services	0.620	0.392	CPI-U for Food Away From Home
(4.) Chemicals[2]	1.100	1.100	Blend of Chemical PPIs
(5.) Medical Instruments	1.014	1.795	PPI for Medical, Surgical, and Personal Aid Devices
(6.) Photographic Supplies[2]	0.096	--	--

Cost Categories	FY 2002-Based RPL Market Basket Cost Weights	Proposed FY 2008-Based RPL Market Basket Cost Weights	Proposed FY 2008-Based RPL Market Basket Price Proxies
(7.) Rubber and Plastics	1.052	1.131	PPI for Rubber and Plastic Products
(8.) Paper and Printing Products	1.000	1.021	PPI for Converted Paper and Paperboard Products
(9.) Apparel	0.207	0.210	PPI for Apparel
(10.) Machinery and Equipment	0.297	0.106	PPI for Machinery and Equipment
(11.) Miscellaneous Products	1.963	0.346	PPI for Finished Goods less Food and Energy
B. All Other Services	8.833	11.414	--
(1.) Labor-related Services	5.111	4.681	--
(a.) Professional Fees: Labor-related[3]	2.892	2.114	ECI for Compensation for Professional and Related Occupations
(b.) Administrative and Business Support Services[4]	n/a	0.422	ECI for Compensation for Office and Administrative Services
(c.) All Other: Labor-Related Services[5]	2.219	2.145	ECI for Compensation for Private Service Occupations
(2.) Nonlabor-Related Services	3.722	6.733	--
(a.) Professional Fees: Nonlabor-Related[3]	n/a	4.211	ECI for Compensation for Professional and Related Occupations
(b.) Financial Services [5]	n/a	0.853	ECI for Compensation for Financial Activities
(c.) Telephone Services	0.240	0.416	CPI-U for Telephone Services
(d.) Postage	0.682	0.630	CPI-U for Postage
(e.) All Other: Nonlabor-Related Services[6]	2.800	0.623	CPI-U for All Items less Food and Energy
5. Capital-Related Costs	10.149	8.392	--
A. Depreciation	6.187	5.519	--

Cost Categories	FY 2002-Based RPL Market Basket Cost Weights	Proposed FY 2008-Based RPL Market Basket Cost Weights	Proposed FY 2008-Based RPL Market Basket Price Proxies
(1.) Fixed Assets	4.250	3.286	BEA chained price index for nonresidential construction for hospitals and special care facilities—vintage weighted (26 years)
(2.) Movable Equipment	1.937	2.233	PPI for Machinery and Equipment—vintage weighted (11 years).
B. Interest Costs	2.775	1.954	--
(1.) Government/Nonprofit	2.081	0.653	Average yield on domestic municipal bonds (Bond Buyer 20 bonds)—vintage-weighted (26 years)
(2.) For Profit	0.694	1.301	Average yield on Moody's Aaa bonds—vintage-weighted (26 years)
C. Other Capital-Related Costs	1.187	0.919	CPI–U for Residential Rent
Total	100.000	100.000	--

Note: Detail may not add to total due to rounding.

[1]Contract Labor is distributed to Wages and Salaries and Employee Benefits based on the share of total compensation that each category represents.

[2]To proxy the Chemicals cost category, we used a blended PPI composed of the PPI for Industrial Gases, the PPI for Other Basic Inorganic Chemical Manufacturing, the PPI for Other Basic Organic Chemical Manufacturing, and the PPI for Soap and Cleaning Compound Manufacturing. For more detail about this proxy, we refer readers to section VII.D.3.c.(10) of the preamble of this proposed rule. In addition, we are proposing to now include expenses related to Photographic Supplies in the Chemicals cost category due to the small cost weight associated with these expenses. We note that, although we would be eliminating the specific cost category, these costs are still accounted for within the RPL market basket.

[3]The "Professional Fees: Labor-related" and "Professional Fees: Nonlabor-related" cost categories were included in one cost category called "Professional Fees" in the FY 2002-based RPL market basket. For more detail about how these new categories were derived, we refer readers to section VII.D.3.f. of the preamble of this proposed rule on the labor-related share.

[4]The Administrative and Business Support Services cost category was contained within the "All Other: Labor-intensive Services" cost category in the FY 2002-based RPL market basket. The "All Other: Labor-intensive Services" cost category is renamed the "All Other: Labor-related Services" cost category for the proposed FY 2008-based RPL market basket.

[5]The "Financial Services" cost category was contained within the "All Other: Non-labor Intensive Services" cost category in the FY 2002-based RPL market basket. The "All Other: Non-labor Intensive Services" cost category is renamed the "All Other: Nonlabor-related Services" cost category for the proposed FY 2008-based RPL market basket.

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(1) Wages and Salaries

We are proposing to use the ECI for Wages and Salaries for Hospital Workers (All Civilian) (BLS series code CIU10262200000000I) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(2) Employee Benefits

We are proposing to use the ECI for Employee Benefits for Hospital Workers (All Civilian) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(3) Electricity

We are proposing to use the PPI for Commercial Electric Power (BLS series code WPU0542). This same proxy was used in the FY 2002-based RPL market basket.

(4) Fuel, Oil, and Gasoline

For the FY 2002-based RPL market basket, this category only included expenses classified under North American Industry Classification System (NAICS) 21 (Mining). We used the PPI for Commercial Natural Gas (BLS series code WPU0552) as a proxy for this cost category. For the proposed FY 2008-based market basket, we are proposing to add costs to this category that had previously been grouped in other categories. The added costs include petroleum-related expenses under NAICS 324110 (previously captured in the miscellaneous category), as well as petrochemical manufacturing classified under NAICS 325110 (previously captured in the chemicals category). These added costs represent 80 percent of the hospital industry's fuel, oil, and gasoline expenses (or 80 percent of this category). Because the majority of the industry's fuel, oil, and gasoline expenses originate from petroleum refineries (NAICS 324110), we are proposing to use the PPI for Petroleum Refineries (BLS series code PCU324110324110) as the proxy for this cost category.

(5) Water and Sewage

We are proposing to use the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(6) Professional Liability Insurance

We are proposing to proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collect commercial insurance premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This method is also used to proxy PLI price changes in the Medicare Economic Index (75 FR 73268). This same proxy was used in the FY 2002-based RPL market basket.

(7) Pharmaceuticals

We are proposing to use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. We note that we are not making a change to the PPI that is used to proxy this cost category. Although there was a recent change to the BLS naming convention for this series, this is the same proxy that was used in the FY 2002-based RPL market basket.

(8) Food: Direct Purchases

We are proposing to use the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(9) Food: Contract Services

We are proposing to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(10) Chemicals

We are proposing to use a blended PPI composed of the PPI for Industrial Gas Manufacturing (NAICS 325120) (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (NAICS 325180) (BLS series code PCU32518–32518–), the PPI for Other Basic Organic Chemical Manufacturing (NAICS 325190) (BLS series code PCU32519–32519–), and the PPI for Soap and Cleaning Compound Manufacturing (NAICS 325610) (BLS series code PCU32561–32561–). Using the 2002 Benchmark I–O data, we found that these NAICS industries accounted for approximately 90 percent of the hospital industry's chemical expenses.

Therefore, we are proposing to use this blended index because we believe its composition better reflects the composition of the purchasing patterns of hospitals than does the PPI for Industrial Chemicals (BLS series code WPU061), the proxy used in the FY 2002-based RPL market basket. Table VII.D–3 below shows the weights for each of the four PPIs used to create the blended PPI, which we determined using the 2002 Benchmark I–O data.

TABLE VII.D-3.--BLENDED CHEMICAL PPI WEIGHTS

Name	Weights (in percent)	NAICS
PPI for Industrial Gas Manufacturing	35%	325120
PPI for Other Basic Inorganic Chemical Manufacturing	25%	325180
PPI for Other Basic Organic Chemical Manufacturing	30%	325190
PPI for Soap and Cleaning Compound Manufacturing	10%	325610

(11) Medical Instruments

We are proposing to use the PPI for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156) to measure the price growth of this cost category. In the 1997 Benchmark I–O data, approximately half of the expenses classified in this category were for surgical and medical instruments. Therefore, we used the PPI for Surgical and Medical Instruments and Equipment (BLS series code WPU1562) to proxy this category in the FY 2002-based RPL market basket. The 2002 Benchmark I–O data show that surgical and medical instruments now represent only 33 percent of these expenses and

that the largest expense category is surgical appliance and supplies manufacturing (corresponding to BLS series code WPU1563). Due to this reallocation of costs over time, we are proposing to change the price proxy for this cost category to the more aggregated PPI for Medical, Surgical, and Personal Aid Devices.

(12) Photographic Supplies

We are proposing to eliminate the cost category specific to photographic supplies for the proposed FY 2008-based RPL market basket. These costs would now be included in the Chemicals cost category because the costs are presently reported as all other chemical products. Notably, although we would be eliminating the specific cost category, these costs would still be accounted for within the RPL market basket.

(13) Rubber and Plastics

We are proposing to use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(14) Paper and Printing Products

We are proposing to use the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(15) Apparel

We are proposing to use the PPI for Apparel (BLS series code WPU0381) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(16) Machinery and Equipment

We are proposing to use the PPI for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(17) Miscellaneous Products

We are proposing to use the PPI for Finished Goods Less Food and Energy (BLS series code WPUSOP3500) to measure the price growth of this cost category. Using this index would remove the double-counting of food and energy prices, which would already be captured elsewhere in the market basket. This same proxy was used in the FY 2002-based RPL market basket.

(18) Professional Fees: Labor-Related

We are proposing to use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS20200000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services. This same proxy was used in the FY 2002-based RPL market basket.

(19) Administrative and Business Support Services

We are proposing to use the ECI for Compensation for Office and Administrative Support Services (Private Industry) (BLS series code CIU2010000220000I) to measure the price growth of this category. Previously these costs were included in the All Other: Labor-intensive category (now renamed the All Other: Labor-related Services category), and were proxied by the ECI for Compensation for Service Occupations. We believe that this compensation index better reflects the changing price of labor associated with the provision of administrative services and its incorporation represents a technical improvement to the market basket.

(20) All Other: Labor-Related Services

We are proposing to use the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(21) Professional Fees: Nonlabor-Related

We are proposing to use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS20200000120000I) to measure the price growth of this category. This is the same price proxy that we are proposing to use for the Professional Fees: Labor-related cost category.

(22) Financial Services

We are proposing to use the ECI for Compensation for Financial Activities (Private Industry) (BLS series code CIU201520A000000I) to measure the price growth of this cost category. Previously these costs were included in the All Other: Nonlabor-intensive category (now renamed the All Other: Nonlabor-related Services category), and were proxied by the CPI for All Items. We believe that this compensation index better reflects the changing price of labor associated with the provision of financial services and its incorporation represents a technical improvement to the market basket.

(23) Telephone Services

We are proposing to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(24) Postage

We are proposing to use the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category. This same proxy was used in the FY 2002-based RPL market basket.

(25) All Other: Nonlabor-Related Services

We are proposing to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. Previously these costs were proxied by the CPI for All Items in the FY 2002-based RPL market basket. We believe that using the CPI for All Items Less Food and Energy would remove the double counting of changes in food and energy prices, as they are already captured elsewhere in the market basket. Consequently, we believe that the incorporation of this proxy would represent a technical improvement to the market basket.

d. Proposed Methodology for Capital Portion of the RPL Market Basket

In the FY 2002-based RPL market basket, we did not have freestanding IRF, freestanding IPF, and LTCH 2002 Medicare cost report data for the capital cost weights, due to a change in the 2002 reporting requirements. Therefore, we used these hospitals' 2001 expenditure data for the capital cost categories of depreciation, interest, and other capital expenses, and aged the data to a 2002 base year using relevant price proxies.

For the proposed FY 2008-based RPL market basket, we are proposing to calculate weights for the proposed RPL market basket capital costs using the same set of FY 2008 Medicare cost reports used to develop the operating share for IRFs, IPFs, and LTCHs. To calculate the proposed total capital cost weight, we first apply the same length of stay edits as applied when calculating the operating cost weights as described above in section VII.D.3.a. of this preamble The resulting proposed capital weight for the FY 2008 base year is 8.392 percent.

Lease expenses are unique in that they are not broken out as a separate cost category in the RPL market basket, but rather are proportionally distributed amongst the cost categories of

Depreciation, Interest, and Other, reflecting the assumption that the underlying cost structure of leases is similar to that of capital costs in general. As was done in the FY 2002-based RPL market basket, we first assumed 10 percent of lease expenses represents overhead and assigned those costs to the Other Capital-Related Costs category accordingly. The remaining lease expenses were distributed across the three cost categories based on the respective weights of depreciation, interest, and other capital not including lease expenses.

Depreciation contains two subcategories: (1) Building and Fixed Equipment; and (2) Movable Equipment. The apportionment between building and fixed equipment and movable equipment was determined using the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs. This methodology was also used to compute the apportionment used in the FY 2002-based RPL market basket (71 FR 27815).

The total Interest expense cost category is split between government/nonprofit interest and for-profit interest. The FY 2002-based RPL market basket allocated 75 percent of the total Interest cost weight to government/nonprofit interest and proxied that category by the average yield on domestic municipal bonds. The remaining 25 percent of the Interest cost weight was allocated to for-profit interest and was proxied by the average yield on Moody's Aaa bonds (70 FR 47912). This was based on the FY 2002-based IPPS capital input price index (70 FR 23406) due to insufficient Medicare cost report data for freestanding IRFs, freestanding IPFs, and LTCHs. For the proposed FY 2008-based RPL market basket, we are proposing to derive the split using the FY 2008 Medicare cost report data on interest expenses for government/nonprofit and for-profit freestanding IRFs, freestanding IPFs, and LTCHs. Based on these data, we calculated a proposed 33/67 split between government/nonprofit and for-profit interest. We believe it is important that this split reflects the latest relative cost structure of interest expenses for RPL providers. As stated above, we first apply the average length of stay edits (as described in section VII.D.3.a. of this preamble) prior to calculating this split. Therefore, we are using cost reports that are reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries. Using data specific to government/nonprofit and for-profit freestanding IRFs, freestanding IPFs, and LTCHs as well as the application of these length of stay edits are the primary reasons for the difference in this split relative to the FY 2002-based RPL market basket.

Because capital is acquired and paid for over time, capital expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital portion of the proposed FY 2008-based RPL market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We are proposing to use the vintage weights to compute vintage-weighted price changes associated with depreciation and interest expense.

Vintage weights are an integral part of the proposed FY 2008-based RPL market basket. Capital costs are inherently complicated and are determined by complex capital purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. The capital portion of the proposed FY 2008-based RPL market basket would reflect the annual price changes associated with capital costs, and would be a useful simplification of the actual capital investment process. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for Medicare capital-related costs. The capital component of the proposed FY 2008-based RPL market basket would reflect the underlying stability of the capital acquisition process and provides hospitals with the ability to plan for changes in capital payments.

To calculate the vintage weights for depreciation and interest expenses, we needed a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital purchases. However, AHA does provide a consistent database back to 1963. We used data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then used data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2008.

In order to estimate capital purchases using data on depreciation expenses, the expected life for each cost category (building and fixed equipment, movable equipment, and interest) is needed to calculate vintage weights. For the FY 2002-based RPL market basket, due to insufficient Medicare cost report data for freestanding IRFs, freestanding IPFs, and LTCHs, we used 2001 Medicare cost reports for IPPS hospitals to determine the expected life of building and fixed equipment and movable equipment (71 FR 27816). The FY 2002-based RPL market basket was based on an expected average life of building and fixed equipment of 23 years. It used 11 years as the average expected life for moveable equipment. We believed that this data source reflected the latest relative cost structure of depreciation expenses for hospitals at the time and was analogous to freestanding IRFs, freestanding IPFs, and LTCHs.

The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated useful life of an asset if depreciation were to continue at current year levels, assuming straight-line depreciation. Following a similar method to what was applied for the FY 2002-based RPL market basket, we are proposing to use the average expected life of building and fixed equipment to be equal to 26 years, and the average expected life of movable equipment to be 11 years. These expected lives are calculated using FY 2008 Medicare cost reports for IPPS hospitals since we are currently unable to obtain robust measures of the expected lives for building and fixed equipment and movable equipment using the Medicare cost reports from freestanding IRFs, freestanding IPFs, and LTCHs.

We also are proposing to use the building and fixed equipment and movable equipment weights derived from FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs to separate the depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation. Year-end asset costs for building and fixed equipment and movable equipment were determined by

multiplying the annual depreciation amounts by the expected life calculations. We then calculated a time series, back to 1963, of annual capital purchases by subtracting the previous year asset costs from the current year asset costs. From this capital purchase time series, we were able to calculate the vintage weights for building and fixed equipment and for movable equipment. Each of these sets of vintage weights is explained in more detail below.

For the proposed building and fixed equipment vintage weights, we used the real annual capital purchase amounts for building and fixed equipment to capture the actual amount of the physical acquisition, net of the effect of price inflation. This real annual purchase amount for building and fixed equipment was produced by deflating the nominal annual purchase amount by the building and fixed equipment price proxy, BEA's chained price index for nonresidential construction for hospitals and special care facilities. Because building and fixed equipment have an expected life of 26 years, the vintage weights for building and fixed equipment are deemed to represent the average purchase pattern of building and fixed equipment over 26-year periods. With real building and fixed equipment purchase estimates available from 2008 back to 1963, we averaged twenty 26-year periods to determine the average vintage weights for building and fixed equipment that are representative of average building and fixed equipment purchase patterns over time. Vintage weights for each 26-year period are calculated by dividing the real building and fixed capital purchase amount in any given year by the total amount of purchases in the 26-year period. This calculation is done for each year in the 26-year period, and for each of the twenty 26-year periods. We used the average of each year across the twenty 26-year periods to determine the average building and fixed equipment vintage weights for the FY 2008-based RPL market basket.

For the proposed movable equipment vintage weights, the real annual capital purchase amounts for movable equipment were used to capture the actual amount of the physical acquisition, net of price inflation. This real annual purchase amount for movable equipment was calculated by deflating the nominal annual purchase amounts by the movable equipment price proxy, the PPI for Machinery and Equipment. This is the same proxy used for the FY 2002-based RPL market basket. Based on our determination that movable equipment has an expected life of 11 years, the vintage weights for movable equipment represent the average expenditure for movable equipment over an 11-year period. With real movable equipment purchase estimates available from 2008 back to 1963, thirty-five 11-year periods were averaged to determine the average vintage weights for movable equipment that are representative of average movable equipment purchase patterns over time. Vintage weights for each 11-year period are calculated by dividing the real movable capital purchase amount for any given year by the total amount of purchases in the 11-year period. This calculation was done for each year in the 11-year period and for each of the thirty-five 11-year periods. We used the average of each year across the thirty-five 11-year periods to determine the average movable equipment vintage weights for the FY 2008-based RPL market basket.

For the proposed interest vintage weights, the nominal annual capital purchase amounts for total equipment (building and fixed, and movable) were used to capture the value of the debt instrument. Because we have determined that hospital debt instruments have an expected life of 26 years, the vintage weights for interest are deemed to represent the average purchase pattern of total equipment over 26-year periods. With nominal total equipment purchase estimates available from 2008 back to 1963, twenty 26-year periods were averaged to determine the average vintage weights for interest that are representative of average capital purchase patterns over time. Vintage weights for each 26-year period are calculated by dividing the nominal total capital purchase amount for any given year by the total amount of purchases in the 26-year period. This calculation is done for each year in the 26-year period and for each of the twenty 26-year periods. We used the average of each year across the twenty 26-year periods to determine the average interest vintage weights for the FY 2008-based RPL market basket. The vintage weights for the capital portion of the FY 2002-based RPL market basket and the FY 2008-based RPL market basket are presented in Table VII.D–4 below.

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TABLE VII.D-4.--FY 2002 AND FY 2008 VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year	Building and Fixed Equipment		Movable Equipment		Interest	
	FY 2002 23 years	FY 2008 26 years	FY 2002 11 years	FY 2008 11 years	FY 2002 23 years	FY 2008 26 years
1	0.021	0.021	0.065	0.071	0.010	0.010
2	0.022	0.023	0.071	0.075	0.012	0.012
3	0.025	0.025	0.077	0.080	0.014	0.014
4	0.027	0.027	0.082	0.083	0.016	0.016
5	0.029	0.028	0.086	0.085	0.019	0.018
6	0.031	0.030	0.091	0.089	0.023	0.020
7	0.033	0.031	0.095	0.092	0.026	0.021
8	0.035	0.033	0.100	0.098	0.029	0.024
9	0.038	0.035	0.106	0.103	0.033	0.026
10	0.040	0.037	0.112	0.109	0.036	0.029
11	0.042	0.039	0.117	0.116	0.039	0.033
12	0.045	0.041	--	--	0.043	0.035
13	0.047	0.042	--	--	0.048	0.038
14	0.049	0.043	--	--	0.053	0.041
15	0.051	0.044	--	--	0.056	0.043
16	0.053	0.045	--	--	0.059	0.046
17	0.056	0.046	--	--	0.062	0.049
18	0.057	0.047	--	--	0.064	0.052
19	0.058	0.047	--	--	0.066	0.053
20	0.060	0.045	--	--	0.070	0.053
21	0.060	0.045	--	--	0.071	0.055
22	0.061	0.045	--	--	0.074	0.056
23	0.061	0.046	--	--	0.076	0.060
24	--	0.046	--	--	--	0.063
25	--	0.045	--	--	--	0.064
26	--	0.046	--	--	--	0.068
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

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After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category. We are proposing to use the same price proxies for the capital portion of the proposed FY 2008-based RPL market basket that were used in the FY 2002-based RPL market basket with the exception of the Boeckh Construction Index. We replaced the Boeckh Construction Index with BEA's chained price index for nonresidential construction for hospitals and special care facilities. The BEA index represents construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers. Although these price indices move similarly over time, we believe that it is more technically appropriate to use an index that is more specific to the hospital industry. We believe these are the most appropriate proxies for hospital capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

The price proxies (prior to any vintage weighting) for each of the capital cost categories are the same as those used for the FY 2006-based Capital Input Price Index (CIPI) as described in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857).

e. Proposed FY 2012 Market Basket Update for LTCHs

For FY 2012 (that is, October 1, 2011 through September 30, 2012), we are proposing to use an estimate of the proposed FY 2008-based RPL market basket update based on the best available data. Consistent with historical practice, we estimate the RPL market basket update for the LTCH PPS based on IHS Global Insight, Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally

recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Based on IGI's first quarter 2011 forecast with history through the 4th quarter of 2010, the projected market basket update for FY 2012 is 2.8 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are proposing a market basket update of 2.8 percent for FY 2012. Furthermore, because the proposed FY 2012 annual update is based on the most recent market basket estimate for the 12-month period (currently 2.8 percent), we also are proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket), we would use such data, if appropriate, to determine the FY 2012 annual update in the final rule. (As discussed in greater detail in section V.A.2. of the Addendum to this proposed rule, we are proposing an annual update of 1.5 percent to the LTCH PPS standard Federal rate for FY 2012 under proposed § 412.523(c)(3)(viii) of the regulations.)

Using the current FY 2002-based RPL market basket and IGI's first quarter 2011 forecast for the market basket components, the FY 2012 market basket update would be 2.8 percent (before taking into account any statutory adjustment). Table VII.D–5 below compares the proposed FY 2008-based RPL market basket and the FY 2002-based RPL market basket percent changes.

TABLE VII.D-5.--FY 2002-BASED AND PROPOSED FY 2008-BASED RPL MARKET BASKET PERCENT CHANGES; FY 2006 THROUGH FY 2014

Fiscal Year (FY)	FY 2002-Based RPL Market Basket Index Percent Change	Proposed FY 2008-Based RPL Market Basket Index Percent Change
Historical data:		
FY 2006	3.9	3.7
FY 2007	3.4	3.4
FY 2008	3.8	3.7
FY 2009	2.5	2.7
FY 2010	2.3	2.2
Average 2006-2010	3.2	3.1
Forecast:		
FY 2011	2.6	2.7
FY 2012	2.8	2.8
FY 2013	2.9	2.9
FY 2014	3.0	3.0
Average 2011-2014	2.8	2.9

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.

Source: IHS Global Insight, Inc. first quarter 2011 forecast.

For FY 2012, the proposed FY 2008-based RPL market basket update (2.8 percent) is the same as the market basket update based on the FY 2002-based RPL market basket. The lower total compensation weight in the proposed FY 2008-based RPL market basket (62.278 percent) relative to the FY 2002-based RPL market basket (65.877 percent), absent other factors, would have resulted in a slightly lower market basket update using the FY 2008-based RPL market basket. However, this impact is partially offset by the larger weight associated with the Professional Fees category. In both market baskets, these expenditures are proxied by the ECI for Compensation for Professional and Related Services. The weight for Professional Fees in the FY 2002-based RPL market basket is 2.892 percent compared to 6.325 percent in the proposed FY 2008-based RPL market basket. The net effect is that the market basket update is the same for FY 2012 based on the current FY 2002-based RPL market basket and the proposed FY 2008-based RPL market basket.

f. Proposed Labor-Related Share

As discussed in section V.B. of the Addendum to this proposed rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS payments to account for differences in LTCH area wage levels (§ 412.525(c)). The labor-related portion of the LTCH PPS standard Federal rate, hereafter referred to as the labor-related share, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index.

The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. Given this, based on our definition of the labor-related share, we are proposing to include in the labor-related share the sum of the relative importance of Wages and Salaries, Employee Benefits,

Professional Fees: Labor-related, Administrative and Business Support Services, All Other: Labor-related Services (previously referred to in the FY 2002-based RPL market basket as labor-intensive), and a portion of the Capital-Related cost weight.

Consistent with previous rebasings, the All Other: Labor-related Services cost category is mostly comprised of building maintenance and security services (including, but not limited to, commercial and industrial machinery and equipment repair, nonresidential maintenance and repair, and investigation and security services). Because these services tend to be labor-intensive and are mostly performed at the hospital facility (and, therefore, unlikely to be purchased in the national market), we believe that they meet our definition of labor-related services.

As stated in the RY 2007 LTCH PPS final rule (71 FR 27829), the labor-related share was defined as the sum of the relative importance of the labor-related share of operating costs (Wages and Salaries, Employee Benefits, Professional Fees, and All Other: Labor-intensive Services), and capital costs of the RPL market basket based on FY 2002 data. Therefore, to determine the labor-related share for the LTCH PPS for FY 2011, we used the FY 2002-based RPL market basket cost weights relative importance to determine the labor-related share for the LTCH PPS.

For the proposed FY 2008-based RPL market basket rebasing, the proposed inclusion of the Administrative and Business Support Services cost category into the labor-related share remains consistent with the current labor-related share because this cost category was previously included in the Labor-intensive cost category. As previously stated, we are proposing to establish a separate Administrative and Business Support Service cost category so that we can use the ECI for Compensation for Office and Administrative Support Services to more precisely proxy these specific expenses.

For the FY 2002-based RPL market basket, we assumed that all nonmedical professional services (including accounting and auditing services, engineering services, legal services, and management and consulting services) were purchased in the local labor market and, therefore, all of their associated fees varied with the local labor market. As a result, we previously included 100 percent of these costs in the labor-related share. In an effort to more accurately determine the share of professional fees that should be included in the labor-related share, we surveyed hospitals regarding the proportion of those fees that go to companies that are located beyond their own local labor market (the results are discussed below).

We continue to look for ways to refine our market basket approach to more accurately account for the proportion of costs influenced by the local labor market. To that end, we conducted a survey of hospitals to empirically determine the proportion of contracted professional services purchased by the industry that are attributable to local firms and the proportion that are purchased from national firms. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and received no comments.

With approval from the Office of Management and Budget (OMB), we contacted a sample of IPPS hospitals and received responses to our survey from 108 hospitals. We believe that these data serve as an appropriate proxy for the purchasing patterns of professional services for LTCHs as they are also institutional providers of health care services. Using data on full-time equivalents (FTEs) to allocate responding hospitals across strata (region of the country and urban/rural status), we calculated post-stratification weights. Based on these weighted results, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

We applied each of these percentages to its respective Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-related costs. The Professional Fees: Labor-related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-related costs. This is the methodology that we used to separate the proposed FY 2008-based RPL market basket professional fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. In addition to the professional services listed above, we also classified expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees cost category as was done in previous rebasings. The NAICS 55 data are mostly comprised of corporate, subsidiary, and regional managing offices, or otherwise referred to as home offices. Formerly, all of the expenses within this category were considered to vary with, or be influenced by, the local labor market and were thus included in the labor-related share. Because many hospitals are not located in the same geographic area as their home office, we analyzed data from a variety of sources in order to determine what proportion of these costs should be appropriately included in the labor-related share.

Using data primarily from the Medicare cost reports and a CMS database of Home Office Medicare Records (HOMER) (a database that provides city and state information (addresses) for home offices), we were able to determine that 19 percent of the total number of freestanding IRFs, freestanding IPFs, and LTCHs that had home offices had those home offices located in their respective local labor markets—defined as being in the same Metropolitan Statistical Area (MSA).

The Medicare cost report requires hospitals to report their home office provider numbers. Using the HOMER database to determine the home office location for each home office provider number, we compared the location of the provider with the location of the hospital's home office. We then placed providers into one of the following three groups:

- Group 1—Provider and home office are located in different States.
- Group 2—Provider and home office are located in the same State and same city.
- Group 3—Provider and home office are located in the same State and different city.

We found that 63 percent of the providers with home offices were classified into Group 1 (that is, different State) and, thus, these providers were determined to not be located in the same local labor market as their home office. Although there were a very limited number of exceptions (that is, providers located in different States but the same MSA as their home office), the 63 percent estimate was unchanged.

We found that 9 percent of all providers with home offices were classified into Group 2 (that is, same State and same city and, therefore, the same MSA). Consequently, these providers were determined to be located in the same local labor market as their home offices.

We found that 27 percent of all providers with home offices were classified into Group 3 (that is, same State and different city). Using data from the Census Bureau to determine the specific MSA for both the provider

and its home office, we found that 10 percent of all providers with home offices were identified as being in the same State, a different city, but the same MSA.

Pooling these results, we were able to determine that approximately 19 percent of providers with home offices had home offices located within their local labor market (that is, 9 percent of providers with home offices had their home offices in the same State and city (and, thus, the same MSA), and 10 percent of providers with home offices had their home offices in the same State, a different city, but the same MSA). We are proposing to apportion the NAICS 55 expense data by this percentage. Thus, we are proposing to classify 19 percent of these costs into the Professional Fees: Labor-related cost category and the remaining 81 percent into the Professional Fees: Nonlabor-related Services cost category.

Using this proposed method and the IGI forecast for the first quarter 2011 of the proposed FY 2008-based RPL market basket, the proposed LTCH labor-related share for FY 2012 is the sum of the FY 2012 relative importance of each labor-related cost category. Consistent with our proposal to update the labor-related share with the most recent available data, the labor-related share for this proposed rule reflects IGI's first quarter 2011 forecast of the proposed FY 2008-based RPL market basket. Table VII.D–6 below shows the proposed FY 2012 relative importance labor-related share using the proposed FY 2008-based RPL market basket and the FY 2011 relative importance labor-related share using the FY 2002-based RPL market basket.

TABLE VII.D-6.--COMPARISON OF THE FY 2011 RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE FY 2002-BASED RPL MARKET BASKET AND THE PROPOSED FY 2012 RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE PROPOSED FY 2008-BASED RPL MARKET BASKET

	FY 2011 Relative Importance Labor-Related Share[1]	Proposed FY 2012 Relative Importance Labor-Related Share[2]
Wages and Salaries	52.449	49.066
Employee Benefits	13.971	13.040
Professional Fees: Labor-Related	2.855	2.073
Administrative and Business Support Services	--	0.416
All Other: Labor-Related Services	2.109	2.094
Subtotal	71.384	66.689
Labor-Related Portion of Capital Costs (46%)	3.887	3.645
Total Labor-Related Share	**75.271**	**70.334**

[1]Published in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50391) and based on the second quarter 2010 IGI forecast.

[2]Based on the first quarter 2011 IGI forecast.

The proposed labor-related share for FY 2012 is the sum of the proposed FY 2012 relative importance of each labor-related cost category, and would reflect the different rates of price change for these cost categories between the base year (FY 2008) and FY 2012. The sum of the proposed relative importance for FY 2012 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All Other: Labor-related Services) would be 66.689 percent, as shown in Table VII.D–6 above. We are proposing that the portion of Capital that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the FY 2002-based RPL market basket. Because the relative importance for Capital-Related Costs would be 7.923 percent of the proposed FY 2008-based RPL market basket in FY 2012, we are proposing to take 46 percent of 7.923 percent to determine the proposed labor-related share of Capital for FY 2012. The result would be 3.645 percent, which we are proposing to add to 66.689 percent for the operating cost amount to determine the total proposed labor-related share for FY 2012. Thus, the labor-related share that we are proposing to use for LTCH PPS in FY 2012 would be 70.344 percent. This proposed labor-related share is determined using the same methodology as employed in calculating all previous LTCH labor-related shares.

E. Proposed Changes to the LTCH Payment Rates and Other Proposed Changes to the FY 2012 LTCH PPS

1. Overview of Development of the LTCH Payment Rates

The LTCH PPS was effective beginning with a LTCH's first cost reporting period beginning on or after October 1, 2002. Therefore, beginning with their FY 2003 cost reporting period, LTCHs were paid, during a 5-year transition period, a total LTCH prospective payment that was comprised of an increasing proportion of the LTCH PPS Federal rate and a decreasing proportion based on reasonable cost-based principles, unless the hospital made a one-time election to receive payment based on 100 percent of the Federal rate, as specified in § 412.533. New LTCHs (as defined at § 412.23(e)(4)) were paid based on 100 percent of the Federal rate, with no phase-in transition payments.

The basic methodology for determining LTCH PPS Federal prospective payment rates is set forth at § 412.515 through § 412.536. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal rate for FY 2012, that is, effective for LTCH discharges occurring on or after October 1, 2011 through September 30, 2012.

For further details on the development of the FY 2003 standard Federal rate, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the LTCH PPS Federal rate, we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (68 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); and FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444).

The proposed update to the LTCH PPS standard Federal rate for FY 2012 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual market basket update to the LTCH PPS standard Federal rate for FY 2012 are discussed below. In addition, as discussed below in section VII.E.3. of this preamble, beginning in FY 2012, in addition to the proposed update factor, we are proposing to make an adjustment to the standard Federal rate to account for the estimated effect of any proposed changes to the area wage level adjustment on estimated aggregate LTCH PPS payments.

2. Proposed FY 2012 LTCH PPS Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. With the initial implementation of the LTCH PPS for FY 2003, we established the use of the excluded hospital with capital market basket as the LTCH PPS market basket (67 FR 56016 through 56017). (For further details on the development of the excluded hospital with capital market basket, we refer readers to the RY 2004 LTCH PPS final rule (68 FR 34134 through 34137).) The development of the initial LTCH PPS standard Federal rate for FY 2003, using the excluded hospital with capital market basket, is discussed in further detail in the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56033).

Beginning in RY 2007, we adopted the rehabilitation, psychiatric, long-term care (RPL) hospital market basket based on FY 2002 data as the appropriate market basket of goods and services under the LTCH PPS for discharges occurring on or after July 1, 2006. As discussed in the RY 2007 LTCH PPS final rule (71 FR 27810), based on our research, we did not develop a market basket specific to LTCH services. We were unable to create a separate market basket specifically for LTCHs at that time due to the small number of facilities and the limited amount of data that was reported. (For further details on the development of the FY 2002-based RPL market basket, we refer readers to the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).)

As discussed in greater detail in section VII.D. of this preamble, we are proposing to revise and rebase the market basket used under the LTCH PPS for FY 2012. Specifically, we are proposing to adopt a newly created FY 2008-based RPL market basket (described in section VII.D. of this preamble). Also, in section VII.D. of this preamble, we discuss our continued interest in exploring the possibility of creating a stand-alone LTCH market basket that reflects the cost structures of only LTCH providers.

b. Revision of Certain Market Basket Updates as Required by the Affordable Care Act

Several provisions of the Affordable Care Act affect the policies and payment rates under the LTCH PPS. Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year through 2019, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in sections 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment (which we refer to as "the multifactor productivity (MFP) adjustment" as discussed in section VII.E.2.d. of this preamble) described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we have adopted the term "fiscal year" (FY) rather than "rate year" (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as "rate year," consistent with our change in the terminology used under the LTCH PPS from "rate year" to "fiscal year," for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we employ "fiscal year" rather than "rate year" for 2011 and subsequent years.

c. Proposed Market Basket Under the LTCH PPS for FY 2012

As noted above and as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50389), when we initially created the FY 2002-based RPL market basket, we were unable to create a separate market basket specifically for LTCHs due, in part, to the small number of facilities and the limited data that were provided in the Medicare cost reports. Over the last several years, however, the number of LTCHs submitting valid

Medicare cost report data has increased. Based on this development, as well as our desire to move from one RPL market basket to three stand-alone and provider-specific market baskets (for IRFs, IPFs, and LTCHs, respectively), we have begun to explore the viability of creating these market baskets for future use. However, as we discussed in the RY 2010 LTCH PPS final rule (74 FR 43967 through 43968), we are conducting further research to assist us in understanding the reasons for the variations in costs and cost structure between freestanding IRFs and hospital-based IRFs. We also are researching the reasons for similar variations in costs and cost structure between freestanding IPFs and hospital-based IPFs. Therefore, we do not believe it is appropriate at this time to propose stand-alone market baskets for IRFs, IPFs, and LTCHs, and we believe that it is appropriate to continue to use the RPL market basket for LTCHs, IRFs, and IPFs under their respective PPSs.

We continue to believe that the RPL market basket appropriately reflects the cost structure of LTCHs, for the reasons discussed when we adopted the RPL market basket for use under the LTCH PPS in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817). For the reasons explained above, we are proposing to continue to use the RPL market basket under the LTCH PPS for FY 2012. However, as discussed in greater detail in section VII.D. of this preamble, we are proposing to rebase and revise the FY 2002-based RPL market basket by creating a proposed FY 2008-based RPL market basket. Currently, we are exploring the viability of creating two separate market baskets from the current RPL market basket: One market basket would include freestanding IRFs and freestanding IPFs and would be used to update payments under both the IPF and IRF payment systems. The other market basket would be a stand-alone LTCH market basket. Depending on the outcome of our research, we may propose a stand-alone LTCH market basket in the next LTCH PPS update cycle. We invite public comment on the possibility of using this type of market basket to update LTCH payments in the future.

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to use the proposed FY 2008-based RPL market basket (described in section VII.D. of this preamble) under the LTCH PPS for FY 2012, which we continue to believe appropriately reflects the cost structure of LTCHs.

d. Productivity Adjustment

Section 1886(m)(3)(A)(i) of the Act specifies that, for FY 2012 and subsequent years, any annual update to the standard Federal rate shall 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, as added by section 3401(a) of the Affordable Care 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, calendar year, cost reporting period, or other annual period) (the "MFP adjustment"). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private non-farm business MFP. We refer readers to the BLS Web site at *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data.

The proposed MFP adjustment that would be applied in determining any annual update to the LTCH PPS standard Federal rate is the same adjustment that is required to be applied in determining the applicable percentage increase under the IPPS under section 1886(b)(3)(B)(i) of the Act. As described in section IV.K.3. of this preamble, we are proposing to derive the FY 2012 MFP adjustment applied to the operating IPPS applicable percentage increase using a projection of MFP that is currently produced by IHS Global Insight, Inc. (IGI). For a detailed description of the model currently used by IGI to project MFP, as well as a description of how the proposed MFP adjustment is calculated for FY 2012, we refer readers to section IV.K.3 of this preamble. The current estimate of the proposed MFP adjustment for FY 2012 based on IGI's first quarter 2011 forecast is 1.2 percent. Consistent with the statute, we are proposing to reduce the proposed FY 2012 market basket update of the LTCH PPS standard Federal rate using this same proposed FY 2012 MFP adjustment.

To determine the proposed market basket update for LTCHs for FY 2012, as reduced by the MFP adjustment, consistent with the approach proposed under the IPPS for FY 2012 (discussed in section IV.K.3. of this preamble), we are proposing that the proposed FY 2012 MFP percentage adjustment be subtracted from the proposed FY 2012 market basket update. We are proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the FY 2012 market basket update and MFP adjustment in the final rule. Following application of the productivity adjustment, the proposed adjusted market basket update (that is, the full market basket increase less the MFP adjustment) is then reduced by the "other adjustment" as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. The proposed market basket update for FY 2012, which reflects both the proposed MFP adjustment and the "other adjustment" as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act, is described in section VII.E.2.e. of this preamble.

e. Proposed Annual Market Basket Update for LTCHs for FY 2012

Consistent with our historical practice, we are proposing to estimate the proposed market basket update based on IGI's forecast using the most recent available data.Based on IGI's first quarter 2011 forecast, the proposed FY 2012 market basket estimate for the LTCH PPS using the proposed FY 2008-based RPL market basket is 2.8 percent. Consistent with our historical practice of using market basket estimates based on the most recent available data, we are proposing that if more recent data are available when we develop the final rule, we would use such data, if appropriate.

Section 1886(m)(3)(A)(i) of the Act specifies that, for FY 2012 (and subsequent years), any annual update to the standard Federal rate shall be reduced by the productivity adjustment (referred to as "the MFP adjustment") described in section 1886(b)(3)(B)(xi)(II) of the Act. Furthermore, section 1886(m)(3)(A)(ii) of the Act specifies that, for each of RYs 2010 through 2019, any annual update to the standard Federal rate shall be reduced by the other adjustment specified in section 1886(m)(4) of the Act. Specifically, section 1886(m)(4)(C) of the Act requires a 0.1 percentage point reduction to the annual update to the LTCH PPS standard Federal rate for FY 2012.

In accordance with section 1886(m)(3)(A)(i) of the Act, we are proposing to reduce the proposed FY 2012 full market basket estimate of 2.8 percent (based on the first quarter 2011 forecast of the proposed FY 2008-based RPL market basket) by the proposed FY 2012 MFP adjustment (that is, the 10-year moving average of MFP for the period ending FY 2012, as described in section VII.E.2.d of this preamble) of 1.2 percent (based on IGI's first quarter 2011 forecast). Following application of the productivity adjustment, the proposed adjusted market basket update of 1.6

percent (2.8 percent minus 1.2 percentage points) is then reduced by 0.1 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(C) of the Act.

Therefore, in this proposed rule, we are proposing to establish an annual market basket update under the LTCH PPS for FY 2012 of 1.5 percent (that is, the most recent estimate of the proposed LTCH PPS market basket update at this time of 2.8 percent less the proposed MFP adjustment of 1.2 percentage points less the 0.1 percentage point required under section 1886(m)(4)(C) of the Act). Accordingly, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (viii), which would specify that the standard Federal rate for FY 2012 is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.5 percent. Again, consistent with our historical practice of using the most recent available data, we are proposing that if more recent data are available when we develop the final rule, we would use such data, if appropriate, in determining the final market basket update under the LTCH PPS for FY 2012. (We note that in section VII.E.3. of this preamble, for FY 2012, we are proposing to adjust the standard Federal rate by an area wage level budget neutrality factor of 0.99723 in accordance with proposed § 412.523(d)(4).)

3. Proposed Budget Neutrality Adjustment for the Changes to the Area Wage Level Adjustment

As described in section V.B. of the Addendum to this proposed rule, when the LTCH PPS was implemented, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal rate to account for differences in LTCH area wage levels at § 412.525(c). The labor-related share of the LTCH PPS standard Federal rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act. Historically, in general, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. However, there are currently no statutory or regulatory requirements that state that any updates or adjustments to the LTCH PPS area wage level adjustment (that is, the wage index or the labor-related share) be budget neutral, such that estimated aggregate LTCH PPS payments would be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment.

As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56015), when we implemented the LTCH PPS, we established a 5-year transition to the full area wage level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable full LTCH PPS wage index values are used to make payments under the LTCH PPS. As discussed in section VII.D. of this preamble, we are proposing to revise and rebase the market basket used under the LTCH PPS for FY 2012, and we are also proposing to update the labor-related share for FY 2012 based on this proposed market basket. We are taking this opportunity to revisit our approach for annually updating the area wage level adjustment. In order to mitigate estimated yearly fluctuations in estimated aggregate LTCH PPS payments, as have been suggested in the past, we have given further consideration to the issue of establishing a budget neutrality requirement for any changes to the area wage level adjustment. Therefore, in this proposed rule, under the broad authority conferred upon the Secretary under section 123 of the BBRA, as amended by section 307(b) of the BIPA, to develop the LTCH PPS, we are proposing that, beginning with the proposed adjustment for area wage levels for FY 2012 (discussed in section V.B. of the Addendum to this proposed rule), any changes to the wage index values or labor-related share would be made in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without such changes to the area wage level adjustment. Accordingly, under § 412.525(c), we are proposing to specify that, beginning in FY 2012, any adjustments or updates made to the area wage level adjustment under this section will be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected.

Under this proposal, we would determine an area wage level adjustment budget neutrality factor that would be applied to the standard Federal rate to ensure that any changes to the area wage level adjustment would be budget neutral such that any changes to the wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Specifically, we are proposing to use the following steps to determine a proposed area wage level adjustment budget neutrality factor that would be applied to the standard Federal rate that would ensure that the proposed FY 2012 update to the wage index values and to the labor-related share are adopted in a budget neutral manner.

- Step 1—We would simulate estimated aggregate LTCH PPS payments using the FY 2011 wage index values as established in Tables 12A and 12B of the Addendum to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50627 through 50646) and the FY 2011 labor-related share of 75.271 percent as established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50391 and 50445).
- Step 2—We would simulate estimated aggregate LTCH PPS payments using the proposed FY 2012 wage index values as shown in Tables 12A and 12B of the Addendum to this proposed rule and the proposed FY 2012 labor-related share of 70.334 percent as discussed in section VII.D.3.f. of this proposed rule.
- Step 3—We would calculate the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2011 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS payments using the proposed FY 2012 area wage level adjustments (calculated in Step 2) to determine the area wage level adjustment budget neutrality factor.
- Step 4—We would then apply the proposed FY 2012 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2012 LTCH PPS standard Federal rate after the application of the proposed FY 2012 annual update (discussed in section V.A.2. of the Addendum to this proposed rule). We are proposing to revise the existing regulations at § 412.523(d) to add a new paragraph (4), which would specify that, beginning in FY 2012, we would adjust the standard Federal rate by a factor that accounts for the estimated effect of any adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments. In this proposed rule, we also are proposing to revise existing § 412.525(c) to reflect our current policy of updating the labor-related share annually.

For this proposed rule, using the steps in the proposed methodology described above, we have determined a proposed

FY 2012 area wage level adjustment budget neutrality factor of 0.99723. Accordingly, in section V.A.2. of the Addendum to this proposed rule, to determine the proposed FY 2012 LTCH PPS standard Federal rate, we are proposing to apply an area wage level adjustment budget neutrality factor of 0.99723, in accordance with proposed § 412.523(d)(4), and therefore, the proposed FY 2012 LTCH PPS standard Federal rate shown in Table 1E reflects this proposed adjustment.

4. Greater Than 25-Day Average Length of Stay Requirement for LTCHs

Section 1886(d)(1)(B) of the Act lists hospitals that are excluded from the IPPS. Section 1886(d)(1)(B)(iv) of the Act specifies the exclusion from the IPPS for "a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days." The average length of stay requirement was established as the sole prerequisite for a hospital seeking to be excluded from the IPPS under this provider category. Section 114(a) of the MMSEA of 2007 amended section 1861 of the Act by adding a new subsection (ccc), which further defined LTCHs. Thus, a hospital's classification as an LTCH has depended, in large part, upon whether an acute care hospital met the greater than 25 days average length of stay requirement. Once the hospital was classified as such under this criterion, the ability for the hospital to continue its exclusion from the IPPS and be paid as an LTCH depended, in part, upon its continuing to meet that criterion.

The regulations at 42 CFR 412.23(e)(1) and (e)(2) set forth the requirements a hospital must meet in order to be excluded from the IPPS and be paid as an LTCH. Specifically, § 412.23(e)(1) requires that a hospital must have a provider agreement under 42 CFR Part 489 to participate as a Medicare hospital, and § 412.23(e)(2) provides that a hospital must meet the LTCH average length of stay of greater than 25 days policy. The methodology for calculating the average length of stay is specified at § 412.23(e)(3). A detailed explanation of the procedural features of the average length of stay policy was included in the FY 2003 LTCH PPS final rule, which implemented the LTCH PPS (67 FR 55970 through 55974)).

In this proposed rule, we are proposing to clarify two existing CMS policies related to the greater than 25 days average length of stay requirement policy: (1) the determination of the average length of stay for a hospital seeking exclusion under the IPPS to be paid as an LTCH or an existing LTCH undergoes a change of ownership; and (2) the inclusion of Medicare Advantage days in calculating the average length of stay.

a. Determination of the Average Length of Stay When There is a Change of Ownership

Under § 412.23(e)(3)(iv) of the regulations, we implemented a policy regarding the application of the average length of stay methodology, where a hospital (that is either seeking LTCH status, or is an existing LTCH) has undergone a change of ownership. Specifically, in the event of a change of ownership, the regulation provides:

"If a hospital has undergone a change of ownership (as described in § 489.18 of this chapter) at the start of a cost reporting period or at any time within the period of at least 5 months of the preceding 6-month period, the hospital may be excluded from the prospective payment system as a long-term care hospital for a cost reporting period if, for the period of at least 5 months of the 6 months immediately preceding the start of the period (including time before the change of ownership), the hospital has the required average length of stay, continuously operated as a hospital, and continuously participated as a hospital in Medicare."

Section 412.23(e)(3)(iv) institutes a procedure by which the average length of stay of a hospital seeking LTCH status or an existing LTCH is evaluated by its fiscal intermediary or MAC to determine whether or not the facility that is being sold meets the requirements for LTCH status. Because the sale of the facility, in effect, ends the seller's cost reporting period (§ 413.24(f)(1)), and triggers the beginning of the purchaser's first cost reporting period, the period of time that is evaluated is the "at least 5 months of the 6 months immediately preceding the period (including time before the change of ownership" to determine the average length of stay that will result in the hospital that meets the requirements for LTCH status. If the average length of stay data indicates that, for this period of time, the hospital met the required average length of stay of greater than 25 days, then the new owner's hospital will achieve IPPS exclusion and LTCH status. On the other hand, if the data indicate that the hospital does not meet the required average length of stay, the hospital will instead be paid under the IPPS under its new ownership. We understand that there has been some confusion in the provider community regarding the specific applicability of this regulation to a change of ownership of an existing LTCH. Accordingly, in this proposed rule, we are proposing to clarify this policy in regulation text by revising § 412.23(e)(3)(iv) to specifically address the circumstance of a hospital that has not as yet been classified as an LTCH and wishes to be classified as an LTCH based on data from the hospital's discharges occurring both before and after the change of ownership. Moreover, in an effort to provide greater clarity, we are also proposing to establish a separate provision in the regulations (proposed paragraph (e)(3)(v) under § 412.23) to directly address LTCH status where there is a change of ownership of an existing LTCH. The sale of an existing LTCH, which triggers the beginning of a new cost reporting period under the new owner (413.24(f)(1)), is a situation where we believe it is appropriate to review whether the hospital that is being sold has been functioning as an LTCH, that is, has been treating patients for on average length of stay of greater than 25 days, before allowing the new owner to continue to be paid for services provided at the hospital under the LTCH PPS. Therefore, we are proposing that where there has been a change of ownership of an existing LTCH, the hospital will continue to be excluded from the inpatient prospective payment system as a long-term care hospital for the cost reporting period beginning with the change of ownership only if for the period of at least 5 months of the 6 months immediately preceding the change of ownership, the hospital meets the required average length of stay. We note that, conversely, under this proposed policy, if the hospital fails to meet the required average length of stay criterion, after this evaluation, and if it is an acute-care hospital, it will be paid instead under the IPPS effective with the day of the change of ownership, that is, the start of the new owner's cost reporting period.

Accordingly, we are proposing to clarify our existing policy as described above by (1) revising existing § 412.23(e)(3)(iv), to specifically address LTCH status in instances where a hospital is seeking IPPS exclusion and payment under the LTCH PPS but a change of ownership has occurred, and (2) proposing to establish a new § 412.23(e)(3)(v) to specifically address the issue of LTCH status for existing LTCHs undergoing a change of ownership.

b. Inclusion of Medicare Advantage (MA) Days in the Average Length of Stay Calculation

With the passage of the Balanced Budget Act of 1997, Medicare beneficiaries were given the option to receive their Medicare benefits through private health insurance plans instead

of through the original Medicare plan (Parts A and B). These programs were known as Medicare+Choice or Part C plans (Section 1851 through 1859 of the Act, implemented in 42 CFR part 422). Pursuant to the *Medicare Prescription Drug, Improvement, and Modernization Act* of 2003, the compensation and business practices changed for insurers that offer these plans, and "Medicare+Choice" plans became known as Medicare Advantage (MA) plans.

When CMS implemented the LTCH PPS beginning in FY 2003, we revised the then-existing policy for calculating the average length of stay for LTCHs described at then § 412.23(e)(2)(i). Under the TEFRA payment system, the average length of stay was determined by "* * * dividing the number of total inpatient days * * * by the total discharges for the hospital's most recent complete cost reporting period * * *" However, beginning with FY 2003, under the newly implemented LTCH PPS, the calculation was based on "dividing the total number of covered and noncovered days of stay of Medicare inpatients * * * by the total Medicare discharges for the hospital's most recent complete cost reporting period" (§ 412.23(e)(3)(i)). The rationale for this change, as noted in the preamble to the FY 2003 LTCH PPS final rule, is that "LTCHs exist as a provider type in order to treat Medicare patients requiring complex long-term hospital-level care. We believe that a hospital's right to qualify for payments under the prospective payment system for LTCHs should result from the actual provision of clinically appropriate care to Medicare LTCH patients * * *" (67 FR 55971).

Although the policy since the start of the LTCH PPS has been for all LTCH patients being paid for by Medicare to be included in the average length of stay calculation, until recently, we were unable to include data for Medicare Advantage (MA) patients in our calculations because our database did not capture discharge data on claims paid by an MA plan. (In contrast, patients who still had private insurance as their primary health coverage and for whom Medicare was a secondary payer, were included in the calculations because the portion of their claims covered by Medicare was paid by Part A and was therefore included in our database.)

On July 20, 2007, we issued Change Request 5647 that required the submission by hospitals (IPPS, IRFs, and LTCHs) of "information only" (not for payment) bills for their MA patients to their fiscal intermediaries or MACs beginning with FY 2007. The stated goal of capturing these MA data was that the data were needed for disproportionate share payments (DSH) under the IPPS, low-income patient (LIP) payments under the IRF PPS, and for short-stay outlier (SSO) payments under the LTCH PPS. An additional one-time notification, Change Request 6821, issued on June 7, 2010, reiterated the requirements of Change Request 5647 for the reporting of MA days for DHS and LIP data and also noted "[i]n addition, this data is used for other purposes such as determining LTCH short stay outlier payments and evaluating the greater than 25 days length of stay requirement of Medicare patients for LTCHs."

Although the inclusion of MA days in the average length of stay calculation has been CMS' policy under the LTCH PPS because, at the outset of the LTCH PPS, we specified that the average length of stay calculation was based on "all covered" and on "all covered days of stay of Medicare patients" (§ 412.23(e)(2)). We acknowledge that, in practice, MA days were not included due to limitations in our ability to capture the data. We have been informed by some members of the provider community that it was not their understanding that MA data should be included in determining a LTCH's average length of stay, and that, in some cases, the inclusion of these data could substantially lower their average length of stay, thus threatening their status as LTCHs. Therefore, we are proposing to clarify our existing policy at 42 CFR 412.23(e)(3) on the calculation of the average length of stay to specify that all data on all Medicare inpatient days, including MA days, shall be included in the average length of stay calculation.

F. Proposed Application of LTCH Moratorium on the Increase in Beds at Section 114(d)(1)(B) of Public Law 110–173 (MMSEA) to LTCHs and LTCH Satellite Facilities Established or Classified as Such Under Section 114(d)(2) of Public Law 110–173

Under section 114(d) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), Congress established one moratorium on the establishment or classification of new LTCHs and LTCH satellite facilities and a second moratorium on the increase in the number of LTCH beds in "existing hospitals and satellite facilities." This section 114(d) provision was amended by section 4302(b) of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) and implemented in interim final rules issued in the **Federal Register** on May 22, 2008, and August 27, 2009 (73 FR 29704 through 29707 and 74 FR 43990 through 43992, respectively), and finalized in the FY 2010 and FY 2011 IPPS/LTCH PPS final rules (74 FR 43985 through 43990 and 75 FR 50397 through 50399, respectively). With the passage of the Affordable Care Act on March 23, 2010, these moratoria were extended under sections 3016 and 10312 for an additional 2 years, through December 29, 2012, and implemented in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50400).

Specific exceptions to each moratorium are included in the statute and permit both the continued establishment or classification of an LTCH or LTCH satellite facility and an increase in LTCH beds at a statutorily defined "existing" hospital or satellite facility, respectively. Under section 114(d)(2) of the MMSEA, as of December 29, 2007, the preclusion on the establishment or classification of a new LTCH or LTCH satellite facility would not apply if the circumstance met one of the following three exceptions:

- The LTCH began its qualifying period for payment as a LTCH under 42 CFR 412.23(e) on or before the date of enactment of the MMSEA (section 114(d)(2)(A)).
- The LTCH has a binding written agreement with an outside, unrelated party for the actual construction, renovation, lease, or demolition for a LTCH and had expended before December 29, 2007, at least 10 percent of the estimated cost of the project or, if less, $2.5 million (section 114(d)(2)(B)).
- The LTCH has obtained an approved certificate of need (CON) in a State where one is required on or before December 29, 2007 (section 114(d)(2)(C)).

Section 114(d)(3) of the MMSEA, as originally enacted, provided an exception to the moratorium on increase in beds at an existing LTCH or LTCH satellite facility, if an existing LTCH or satellite facility is located in a State where there is only one other LTCH; and the LTCH or satellite facility requests an increase in beds following the closure or decrease in the number of beds of another LTCH in the State. Section 4302(b) of the ARRA amended this MMSEA provision to specify an additional exception to the moratorium on the increase in bed number if the hospital or facility obtained a certificate of need for an increase in beds that is in a State for which such certificate of need is required and that was issued on or after April 1, 2005, and before December 29, 2007.

In implementing these two moratorium provisions, we required that each hospital or entity submit details of its individual circumstance for evaluation by CMS regional offices and contractors in order to determine whether a specific statutory exception was applicable to the particular situation (74 FR 43985 through 43990). We note that, based upon these exceptions (73 FR 29707), CMS records indicate that, as of January 1, 2011, 50 new LTCHs and 8 new LTCH satellites have been established or classified after December 29, 2007, the date MMSEA was enacted. (Data on additional beds developed in existing LTCHs and LTCH satellite facilities under the CON exception provided by section 4302(b) of the ARRA are maintained by States.)

Sections 3106 and 10312 of the Affordable Care Act provided a 2-year extension of both moratoria initially established by section 114(d)(1) of the MMSEA (which provided for an original 3-year application), indicating that Congress continues to believe that it is appropriate to continue to stem the increase in the number of LTCHs and LTCH satellite facilities and LTCH beds.

As noted above, section 114(d)(1)(B) of the MMSEA established a moratorium on the increase of LTCH beds in existing LTCHs or satellite facilities. Section 114(d)(4) of the MMSEA defines "an existing hospital or satellite facility" as a hospital or satellite facility that received payment under the LTCH PPS as of December 29, 2007, the date of enactment of the MMSEA. By definition, LTCHs or satellite facilities that were established or classified as such under an exception at section 114(d)(2) to the moratorium under section 114(d)(1)(A) first received payments under the LTCH PPS after December 29, 2007, and therefore, would not fall under the definition of "an existing hospital or satellite facility" to whom the moratorium on the increase in bed numbers at section 114(d)(1)(B) applies. However, we do not believe that it was Congress' intent to allow this subset of hospitals and satellite facilities established or classified after the enactment of MMSEA unlimited bed growth and expansion. Continued Congressional concern regarding the increase in the number of LTCHs and satellite facilities and LTCH beds is indicated in the 2-year extension of the moratorium provided by sections 3106 and 10312 of the Affordable Care Act.

Section 123 of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA of 1999) (Pub. L. 106–113), as amended by section 307 (b) of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), confers upon the Secretary discretion in creating the LTCH PPS as the payment system for LTCHs beginning in FY 2003. Furthermore, the Secretary has authority, under the general rulemaking authority of sections 1102(a) and 1871(a) of the Act, to establish rules and regulations as necessary to administer the Medicare program and for the efficient administration of the Medicare program. Consistent with these authorities, therefore, we are proposing that, effective October 1, 2011, the moratorium established under section 114(d)(1)(B) of the MMSEA, and implemented at 42 CFR 412.23(e)(7) be applied to those LTCHs and LTCH satellite facilities established or classified as such pursuant to the exceptions at section 114(d)(2) to the moratorium specified under section 114(d)(1)(B) of the MMSEA, as implemented at 42 CFR 412.23(e)(6). Specifically, we are proposing to limit the number of beds in these facilities to the number of beds that were certified by Medicare at the LTCH or satellite facility when it was first paid under the LTCH PPS. We are proposing to amend § 412.23 by adding a new paragraph (e)(8) to specify this proposed policy. We believe that this proposed policy captures the essence of the original statutory moratoria—which was to limit growth in the number of LTCHs and LTCH satellite facilities and LTCH beds payable under Medicare—while recognizing the inherent fairness in allowing those projects already underway that represented substantial investment, planning, and State commitment to be completed.

VIII. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2011 "Report to the Congress: Medicare Payment Policy" and have given the recommendations in the report consideration in conjunction with the policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2012 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's Web site at: *http://www.medpac.gov.*

IX. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are now available on compact disc (CD) format. However, many of the files are available on the Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS.* Data files and the cost for each file, if applicable, are listed below. Anyone wishing to purchase data tapes, cartridges, or diskettes should submit a written request along with a company check or money order (payable to CMS–PUF) to cover the cost of the following address: Centers for Medicare & Medicaid Services, Public Use Files, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520, (410) 786–3691. Files on the Internet may be downloaded without charge.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, Parts II and III from FY 2008 Medicare cost reports used to create the proposed FY 2012 prospective payment system wage index. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.K. of the preamble of this proposed rule.

Processing Year	Wage Data Year	PPS Fiscal Year
2011	2008	2012
2010	2007	2011
2009	2006	2010
2008	2005	2009
2007	2004	2008

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

Periods Available: FY 2007 through FY 2012 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the 2007–2008 occupational mix survey data to be used to compute the occupational mix adjustment wage indexes. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.K. of the preamble of this proposed rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

Period Available: FY 2012 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

Period Available: FY 2012 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

Periods Available: FY 2005 through FY 2012 IPPS Update.

5. FY 2012 IPPS SSA/FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Social Security Administration (SSA) and the Federal Information Processing Standards (FIPS), county name, and a historical list of Metropolitan Statistical Areas (MSAs).

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage.*

Period Available: FY 2012 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: Internet at: *http://www.cms.hhs.gov/CostReports/02_HospitalCostReport.asp* and Compact Disc (CD).

File Cost: $100.00 per year.

7. Provider-Specific File

This file is a component of the PRICER program used in the fiscal intermediary's or the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: Internet at: *http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/03_psf_text.asp*

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number as published in each year's update of the Medicare hospital inpatient prospective payment system. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*

Periods Available: FY 1985 through FY 2012.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay as published in the **Federal Register**. There are two versions of this file as published in the **Federal Register**.

- Notice of proposed rulemaking.
- Final rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*

Periods Available: FY 2005 through 2012 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital impatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, Minimum Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking.
- Final rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage* and *http://www.cms.hhs.gov/AcuteInpatientPPS/HIF/list.asp#TopOfPage*

Periods Available: FY 1994 through FY 2012 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR tables are "Before Outliers

Removed" and the AOR is "After Outliers Removed." (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Periods Available: FY 2006 through FY 2012 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-based Statistical Area (CBSA). The file supports the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2012 IPPS Update.

For further information concerning these data tapes, contact the CMS Public Use Files Hotline at (410) 786–3691.

Commenters interested in discussing any data used in constructing this proposed rule should contact Nisha Bhat at (410) 786–5320.

B. Collection of Information Requirements

1. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for Add-On Payments for New Services and Technologies

Section II.I.1. of the preamble of this proposed rule discusses add-on payments for new services and technologies. Specifically, this section states that applicants for add-on payments for new medical services or technologies for FY 2012 must submit a formal request. A formal request includes a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement. In addition, the request must contain a significant sample of the data to demonstrate that the medical service or technology meets the high-cost threshold. We detailed the burden associated with this requirement in the September 7, 2001, IPPS final rule (66 FR 46902). As stated in that final rule, collection of the information for this requirement is conducted on an individual case-by-case basis. We believe the associated burden is thereby exempt from the PRA as stipulated under 5 CFR 1320.3(h)(6). Similarly, we also believe the burden associated with this requirement 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. This information collection does not impact 10 or more entities in a 12-month period. In FYs 2008, 2009, 2010, 2011, and 2012, we received 1, 4, 5, 3, and 3 applications, respectively.

3. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

The Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. This Program expanded our voluntary Hospital Quality Initiative. The Hospital IQR Program originally consisted of a "starter set" of 10 quality measures. OMB approved the collection of information associated with the original starter set of quality measures under OMB control number 0938–0918.

We added additional quality measures to the Hospital IQR Program and submitted the information collection request to OMB for approval. This expansion of the Hospital IQR measures was part of our implementation of section 5001(a) of the DRA. New section 1886(b)(3)(B)(viii)(III) of the Act, added by section 5001(a) of the DRA, requires that the Secretary expand the "starter set" of 10 quality measures that were established by the Secretary as of November 1, 2003, to include measures "that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings." The burden associated with these reporting requirements is currently approved under OMB control number 0938–1022. For the FY 2014 and FY 2015 payment updates, we intend to seek OMB approval for a revised information collection request using the same OMB control number (0938–1022). In the revised request, we will add five measures that we adopted in the FY 2011 IPPS/LTCH PPS final rule (four chart-abstracted measures and an HAI measure (Surgical Site Infection (SSI)) to be collected via NSHN for the FY 2014 payment determination. In addition, we are proposing to add two HAI measures (CLIP and CAUTI) also to be collected via NHSN, one structural measure and one claims-based measure that we are proposing in this proposed rule to adopt for the FY 2014 payment determination. We estimate that the proposed changes to our FY 2014 payment determination measure set would increase the collection burden on hospitals by approximately 4,250,175 hours per year. Because the currently approved CDC information collection request for the NHSN (OCN: 0920–0666) does not include all of the respondents associated with the IQR program, we intend to request a separate OMB control number for the NHSN proposal.

With respect to the four new chart-abstracted measures for the FY 2014 payment determination, hospitals would be required to submit data on patients who receive inpatient acute care hospital services. Specifically, with respect to the two EDT measures and two Global Immunization measures, hospitals would need to collect information on patients who receive inpatient acute care hospital services regarding EDT, as well as flu and pneumonia vaccinations information for all inpatients for which hospitals currently collect only for patients

admitted for pneumonia. We estimate that hospitals would incur an additional 3,500,000 burden hours resulting from the addition of these four measures for the FY 2014 payment determination. We estimate that hospitals would submit approximately 3,500,000 cases annually for these 4 measures, and the information needed to calculate these measures requires an average of 1 hour to abstract from medical records for each case.

The HAI measure (Surgical Site Infection (SSI)) that we adopted in the FY 2011 IPPS/LTCH PPS final rule for the FY 2014 payment determination and the two HAI measures that we are proposing to add for the FY 2014 payment determination (CLIP and CAUTI) are structured to keep additional burden to a minimum because they are to be collected via NHSN. More than 4,000 hospitals in 29 States are already using NHSN to comply with State-mandated reporting. Although this will add burden for hospitals, we believe that the additional burden will be lessened because hospitals will already be using NHSN to report the CLABSI measure for the FY 2013 payment determination. In addition, as mentioned above, not all hospitals will experience any additional burden because many hospitals already submit data to this system either voluntarily or as part of mandatory State reporting requirements for HAIs. The burden associated with these proposals is the time and effort associated with collecting and submitting the additional data. We estimate that hospitals will need about 750,000 additional hours to report Surgical Site Infection (SSI), CLIP, and CAUTI event data and denominator information into the system.

The structural measure we are proposing to add for the FY 2014 payment determination would require hospitals to indicate whether they are participating in a systematic qualified clinical database for registry for General Surgery and, if so, to identify the registry. If this measure is finalized, we estimate that 3,500 hospitals will spend about 5 minutes each to answer this question each year, resulting in an estimated total increase of 175 hours in terms of the total burden to hospitals each year.

We are also proposing to add one new claims-based measure for the FY 2014 payment determination. We do not believe that this proposed claims-based measure, if finalized, will create any additional burden for hospitals because it would be collected and calculated by CMS based on the Medicare FFS claims the hospitals have already submitted to CMS.

We believe that the overall burden on hospitals will be reduced to some extent by the policy we finalized in the FY 2011 IPPS/LTCH PPS final rule to retire two measures (PN–2 and PN–7) beginning with the FY 2014 payment determination. Burden will be further reduced by our proposal in this proposed rule to retire eight additional measures (AMI–1 Aspirin at Arrival, AMI–3 ACE/ARB, AMI–4 Smoking Cessation, AMI–5 Beta-Blocker at Discharge, HF–4 Smoking Cessation, PN–4 Smoking Cessation, PN–5c Antibiotic within 6 Hours of Arrival and SCIP Inf-6 Appropriate Hair Removal) beginning with the FY 2014 payment determination. We estimate that if we finalize these proposals, the burden to hospitals will be reduced by a total of 740,000 hours as a result of retiring these eight measures, including reductions of 170,000 hours for abstracting AMI measures, 220,000 hours for abstracting PN measures, 50,000 hours for abstracting HF measures, and 300,000 hours for abstracting SCIP measures.

We also are proposing to add two new chart-abstracted measure sets to the Hospital IQR Program for FY 2015: Stroke (eight measures) and Venous Thromboembolism (VTE) (six measures). Both measure sets are of great importance to the Medicare population, with stroke affecting about 795,000 people each year (American Stroke Association). Both stroke and VTE measures are currently collected by the Joint Commission for accreditation and certification purposes. Both measure sets use complimentary data elements to our current SCIP, VTE, and AMI measure sets, thus reducing the chart-abstraction burden. The burden associated with this proposal is the time and effort associated with collecting and submitting the additional data. We estimate that each proposed chart abstracted measure set will require about 1 hour to abstract. We anticipate the number of subsection (d) hospitals participating in the Hospital IQR Program to be approximately 3,500. The number of charts to be abstracted by all participating hospitals is estimated to be 180,000 per year for the proposed Stroke measure set, and 6,000,000 per year for the proposed VTE measure set. In total, our proposal to add Stroke and VTE measures is estimated to increase the burden to hospitals by 6,180,000 hours per year.

We also are proposing to add three new HAI measures to be collected via NHSN to the Hospital IQR Program for FY 2015: (1) Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia measure; (2) C. *Difficile* SIR measure; and (3) Healthcare Personnel Influenza vaccination measure. The information needed for these measures would be collected via NHSN, and, therefore, is structured to keep additional burden to a minimum because more than 4,000 hospitals in 29 States are already using NHSN to comply with State-mandated reporting. Although this will add burden to hospitals, the initial setup and acclimation to the NHSN system will have already occurred with the adoption of the CLABSI measure for all hospital IQR for the FY 2013 payment determination. In addition, as mentioned above, not all hospitals will experience any additional burden since many hospitals already submit data to this system either voluntarily or as part of mandatory State reporting requirements for HAIs. The burden associated with this section is the time and effort associated with collecting and submitting the additional data. With respect to the new HAI proposed measures for the FY 2015 payment determination, we estimate that an additional 1,500,000 burden hours per year (500,000 hours per measure) would be incurred by hospitals to report data on these measures.

We estimate that our proposed changes to our FY 2015 Hospital IQR Program measure set will increase the collection burden to hospitals by approximately 6,780,000 hours per year.

We have stated our intention to explore mechanisms for data submission using electronic health records (EHRs) (73 FR 48614; 74 FR 43866, 43892; 75 FR 50189). Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, the adoption of measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and burden to hospitals. We believe that automatic collection and reporting of data through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and that at a future date, such as FY 2015, hospitals will be able to switch solely to EHR-based reporting of data that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

4. ICRs for the Occupational Mix Adjustment to the Proposed FY 2012 Index (Hospital Wage Index Occupational Mix Survey)

Section II.D. of the preamble of this proposed rule discusses the occupational mix adjustment to the proposed FY 2012 wage index. While the preamble does not contain any new ICRs, it is important to note that there is an OMB approved information collection request associated with the hospital wage index.

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data at least once every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program in order to construct an occupational mix adjustment to the wage index. We collect the data via the occupational mix survey.

The burden associated with this information collection requirement is the time and effort required to collect and submit the data in the Hospital Wage Index Occupational Mix Survey to CMS. The aforementioned burden is subject to the PRA; however, it is currently approved under OMB control number 0938–0907, with an expiration date of February 28, 2013.

5. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.I.3. of the preamble of this final rule discusses revisions to the wage index based on hospital redesignations. As stated in that section, under section 1886(d)(10) of the Act, the MGCRB has the authority to accept short-term IPPS hospital applications requesting geographic reclassification for wage index or standardized payment amounts and to issue decisions on these requests by hospitals for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and effort necessary for an IPPS hospital to complete and submit an application for reclassification to the MGCRB. While this requirement is subject to the PRA, the associated burden is currently approved under OMB control number 0938–0573, with an expiration date of December 31, 2011.

6. ICRs for the Proposed Quality Reporting Program for LTCHs

In section VII.C. of this preamble, we are proposing three quality reporting measures for LTCHs for FY 2014: (1) Catheter Associated Urinary Tract Infections (CAUTI); (2) Central Line Associated Blood Stream Infection Event (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened.

We are proposing to collect the proposed HAI CLABSI and CAUTI quality measures through the use of the CDC/NHSN (*http://www.cdc.gov/nhsn/*). We will require that LTCH facilities report data on each patient in their facility who has been diagnosed with either a catheter associated urinary tract infection or a central line associated bloodstream infection.

The NHSN is a secure, Internet-based surveillance system which is maintained and managed by CDC. Many LTCHs already submit data to the NHSN either voluntarily or as part of mandatory State reporting requirements for HAIs. There are currently 435 LTCHs in operation in the United States and, according to CDC, 80 of these LTCHs already submit HAI data to NHSN. For these LTCHs, the burden of complying with the requirements of the proposed quality reporting program will be reduced because of familiarity with the NHSN submission process.

We require IPPS hospitals to report data regarding certain HAIs via NHSN as part of the Hospital IQR Program. We adopted the CLABSI quality measure under the Hospital IQR Program for the FY 2013 payment determination and are proposing to adopt the CAUTI measure for the FY 2014 payment determination. In addition, hospitals in 29 States are already using NHSN, and CDC supports more than 4,000 hospitals that are already using NHSN. Many LTCHs are integrated into or are part of large inpatient hospital systems. We believe that these hospital systems have gained the requisite knowledge and experience with the submission of data about HAIs via NHSN, under the Hospital IQR Program, State law, or voluntarily. Therefore, the transition to reporting HAIs via the NHSN for these LTCHs may be less burdensome.

The burden associated with these proposed quality measures is the time and effort associated with collecting and submitting the data concerning CAUTI and CLABSI to NHSN for LTCHs that are not currently reporting such data. For LTCHs that already submit data regarding these HAIs to NHSN, there should be little, if any, additional burden. For LTCHs who submit data to NHSN for other HAIs, but not CAUTI and CLABSI data, then there may be some burden. However, we believe that this burden will be significantly decreased because these LTCHs are already enrolled in the NHSN system and are already familiar with the NHSN data submission process.

There are currently 435 LTCHs in the United States paid under the LTCH PPS. We estimate that each LTCH would submit approximately 12 NHSN submissions (6 CAUTI and 6 CLABSI) per month (144 per LTCH annually). This equates to a total of approximately 62,640 submissions of HAI data to NHSN from all LTCHs per year. We estimate that each NHSN assessment will take approximately 25 minutes to complete. This time estimate consists of 10 minutes of clinical (for example, nursing time) needed to collect the clinical data and 15 minutes of clerical time necessary to enter the data into the NHSN data base. Based on this estimate, we expect each LTCH would expend 300 minutes (5 hours) per month and 60 hours per year reporting to NHSN. Therefore, the total estimated annual hourly burden to all LTCHs in the U.S. for reporting to NHSN is 26,100 hours. The estimated cost per submission is estimated at $12.07. These costs are estimated using an hourly wage for a Registered Nurse of $41.59 and a Medical Billing Clerk/Data Entry person of $20.57 (U.S. Bureau of Labor Statistics data). Therefore, we estimate that the annual cost per each LTCH provider would be $1,739 and the total yearly cost to all LTCHs for the submission of CAUTI and CLABSI data to NHSN would be $760,676.[60] While the aforementioned requirements are subject to the PRA, we believe the associated burden hours are accounted for in the information collection request currently approved OCN 0920–0666.

With respect to the proposed pressure ulcer measure, we are proposing that we would post the specification for the pressure ulcer measure on our Web site along with the specific data elements necessary to be collected. We expect that the specific data items needed are part of the Continuity Assessment Record & Evaluation (CARE) instrument. We developed the CARE as required by section 5008 of the Deficit Reduction Act of 2005. CARE is a standardized assessment instrument that could be used across all postacute care sites to measure functional status and other factors during treatment and at discharge from each provider.

Because the CMS CARE pressure ulcer data set has not previously been introduced in the LTCH setting, there will be some initial burdens associated with the introduction of this data assessment tool. These initial costs would mainly be incurred in the

[60] Nursing Time—24 hours @ $41.59 per hour = $998.16/$998.16 × 435 LTCHs = $434,200. Admin Time—36 hours @ $20.57 per hour = $740.52/$740.52 × 435 LTCHs = $326,476. TOTAL = $434,200 + $326,476 = $760,676.

training of the facility staff. However, there should be little, if any, additional education required, in regards to the collection of the data, because pressure ulcer assessment should be a vital part of good patient care and daily in-house patient chart documentation.

We are proposing to require that the CARE pressure ulcer assessment be performed on each patient in a LTCH upon admission and again upon discharge. We believe that it is necessary to obtain admission and discharge pressure ulcer assessments on all patients admitted to LTCH facilities in order to obtain full and complete statistical data regarding the quality of care provided by the facility to the patients receiving care in that facility. The delivery of high quality care in the LTCH setting is imperative. We believe that collecting quality data on all patients in the LTCH setting supports CMS' mission to insure quality care for Medicare beneficiaries. Collecting data on all patients provides the most robust and accurate reflection of quality in the LTCH setting. Accurate representation of quality provided in LTCHs is best conveyed using data related to pressure ulcers on all LTCH patients regardless of payor, using a subset of the CARE data set. An admission assessment is necessary in order to assess for either the presence or absence of pressure ulcers upon admission. If pressure ulcers are detected upon admission, then they must be properly assessed, staged and documented. Upon discharge, an assessment is needed to determine if any worsening of the pressure ulcers occurred during the LTCH stay. If no pressure ulcers had been noted on the admission assessment, then a discharge pressure ulcer assessment would be necessary in order to assess whether the patient had developed any new pressure ulcers during the LTCH stay.

At this time, CMS has not completed development of the information collection instrument that LTCHs would have to submit to comply with the aforementioned reporting requirements regarding the CARE pressure ulcer assessment. Because the forms are still under development, we cannot assign a complete burden estimate at this time. Once the forms are available, we will publish the required 60-day and 30-day **Federal Register** notices to solicit public comments on the instrument and to announce the submission of the information collection request to OMB for its review and approval.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–1518–P, Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov.*

C. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 476

Health care, Health professional, Health record, Peer Review Organization (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this proposed rule, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR Chapter IV as follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. 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 Pub. L. 106–113 (113 Stat. 1501A–332).

2. Section 412.23 is amended by—

a. In paragraph (e)(3)(i), removing the cross-reference "paragraph (e)(3)(ii) through (e)(3)(iv) of this section" and adding in its place the cross-reference "paragraphs (e)(3)(ii) through (e)(3)(v) of this section".

b. Revising paragraph (e)(3)(iv).

c. Adding a new paragraph (e)(3)(v).

d. Adding a new paragraph (e)(8).

The revision and additions read as follows:

§ 412.23 Excluded hospitals: Classifications.

* * * * *

(e) * * *

(3) * * *

(iv) If a hospital seeks exclusion from the inpatient prospective payment system as a long-term care hospital and a change of ownership (as described in § 489.18 of this chapter) occurs within the period of at least 5 months of the 6-month period preceding its petition for long-term care hospital status, the hospital may be excluded from the inpatient prospective payment system as a long-term care hospital for the next cost reporting period if, for the period of at least 5 months of the 6 months immediately preceding the start of the cost reporting period for which the hospital is seeking exclusion from the inpatient prospective payment system as a long-term care hospital (including time before the change of ownership), the hospital has met the required average length of stay, has continuously operated as a hospital, and has continuously participated as a hospital in Medicare.

(v) For periods beginning on or after October 1, 2011, a hospital that is excluded from the prospective payment system as a long-term care hospital that plans to undergo a change of ownership (as described in § 489.18 of this chapter) must notify its fiscal intermediary or MAC within 30 days of the effective date of such change of ownership, as specified in § 424.516(d)(1)(i) of this subchapter. The hospital will continue to be excluded from the inpatient prospective payment system as a long-term care hospital for the cost reporting period following the change of ownership only if, for the period of at least 5 months of the 6 months immediately preceding the start of the hospital's next cost reporting period before the change of ownership, the hospital meets the required average length of stay (calculated in accordance with paragraph (e)(3)(i) of this section).

* * * * *

(8) *Application of LTCH moratorium on the increase in beds at section 114(d)(1)(B) of Public Law 110–173 to LTCHs and LTCH satellite facilities established or classified as such under section 114(d)(2) of Public Law 110–173.* Effective for the period beginning October 1, 2011, and ending December 28, 2012, for long-term care hospitals and long-term care hospital satellite facilities established under paragraph (e)(6)((ii) of this section for the period beginning December 29, 2007, and

ending September 30, 2011, the moratorium at paragraph (e)(7) applies and the number of Medicare-certified beds must not be increased beyond the initial number of Medicare-certified beds established under paragraph (e)(6)(ii) of this section.

* * * * *

3. Section 412.64 is amended by adding a new paragraph (d)(1)(iv) to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(iv) For fiscal year 2012, the percentage increase in the market basket index less a multifactor productivity adjustment (as determined by CMS) and less 0.1 percentage points for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas.

* * * * *

4. Section 412.105 is amended by revising paragraph (b)(4) to read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(b) * * *

(4) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, ancillary labor/delivery services, or inpatient hospice services;

* * * * *

5. Section 412.106 is amended by revising paragraph (a)(1)(ii)(B) to read as follows:

§ 412.106 Special treatment: Hospitals that service a disproportionate share of low income patients.

(a) * * *

(1) * * *

(ii) * * *

(B) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or inpatient hospice services;

* * * * *

6. A new § 412.140 is added to Subpart H to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Review (IQR) Program.

(a) *Participation in the Hospital IQR Program.* In order to participate in the Hospital IQR Program, a subsection (d) hospital must—

(1) Register on QualityNet.org, before it begins to report data;

(2) Identify and register a QualityNet Administrator as part of the registration process under paragraph (a)(1) of this section; and

(3) Submit a completed Notice of Participation Form to CMS if the hospital is participating in the program for the first time, has previously withdrawn from the program and would like to participate again, or has received a new CMS Certification Number (CNN).

(i) A hospital that would like to participate in the program for the first time (and to which paragraph (a)(3)(ii) of this section does not apply), or that previously withdrew from the program and would now like to participate again, must submit to CMS a completed Notice of Participation Form by December 31 of the fiscal year preceding the fiscal year in which it wishes to participate.

(ii) A hospital that has received a new CCN and would like to participate in the program must submit a completed Notice of Participation Form to CMS no later than 180 days from the date identified as the open date on the approved CMS OSCAR system.

(b) *Withdrawal from the Hospital IQR Program.* CMS will accept Hospital IQR Program withdrawal forms from hospitals on or before August 15 of the fiscal year preceding the fiscal year for which a Hospital IQR payment determination will be made.

(c) *Submission and validation of Hospital IQR Program data.*

(1) *General rule.* Except as provided in paragraph (c)(2) of this section, subsection (d) hospitals that participate in the Hospital IQR Program must submit to CMS data on measures selected under section 1886(b)(3)(B)(viii) of the Act in a form and manner, and at a time, specified by CMS. A hospital must begin submitting data on the first day of the quarter following the date that the hospital submits a completed Notice of Participation form under paragraph (a)(3) of this section.

(2) *Exception.* Upon request by a hospital, CMS may grant an extension or waiver of one or more data submission deadlines in the event of extraordinary circumstances beyond the control of the hospital. Specific requirements for submission of a request for an extension or waiver are available onQualityNet.org.

(d) *Validation of Hospital IQR Program data.* CMS may validate one or more measures selected under section 1886(b)(3)(B)(viii) of the Act by reviewing patient charts submitted by selected participating hospitals.

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS a sample of patient charts that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the patient charts to CMS or its contractor within 30 days of the date identified on the written request.

(2) A hospital meets the validation requirement with respect to a fiscal year if it achieves a 75-percent score, as determined by CMS.

(e) *Reconsiderations and appeals of Hospital IQR Program decisions.*

(1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital IQR Program for a particular fiscal year. Except as provided in paragraph (c)(2) of this section, a hospital must submit a reconsideration request to CMS no later than 30 days from the date identified on the Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter provided to the hospital.

(2) A reconsideration request must contain the following information:

(i) The hospital's CMS Certification Number (CCN);

(ii) The name of the hospital;

(iii) Contact information for the hospital's chief executive officer and QualityNet system administrator, including each individual's name, e-mail address, telephone number, and physical mailing address;

(iv) A summary of the reason(s), as set forth in the Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter, that CMS concluded the hospital did not meet the requirements of the Hospital IQR Program;

(v) A detailed explanation of why the hospital believes that it complied with the requirements of the Hospital IQR Program for the applicable fiscal year;

(vi) Any evidence that supports the hospital's reconsideration request, including copies of patient charts, e-mails and other documents; and

(vii) If the hospital has requested reconsideration on the basis that CMS concluded it did not meet the validation requirement set forth in paragraph (d) of this section, the reconsideration request must contain the following additional information:

(A) A copy of each patient chart that the hospital timely submitted to CMS or its contractor in response to a request made under paragraph (d)(1) of this section; and

(B) A detailed explanation identifying which data the hospital believes was improperly validated by CMS and why the hospital believes that such data are correct.

(3) 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 under Part 405, Subpart R of this chapter.

7. Section 412.211 is amended by adding a new paragraph (c)(4) to read as follows:

§ 412.211 Puerto Rico rates for Federal fiscal year 2004 and subsequent fiscal years.

* * * * *

(c) * * *

(4) For fiscal year 2012 and subsequent fiscal years, the applicable percentage increase specified in § 412.64(d).

* * * * *

8. Section 412.523 is amended by—

a. Adding a new paragraph (c)(3)(viii).

b. Adding a new paragraph (d)(4).

The additions to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(viii) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2011, and ending September 30, 2012.* The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2011, and ending September 30, 2012, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.5 percent. The standard Federal rate is adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

(d) * * *

(4) *Changes to the adjustment for area wage levels.* Beginning in FY 2012, CMS adjusts the standard Federal rate by a factor that accounts for the estimated effect of any adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments.

* * * * *

9. Section 412.525 is amended by revising paragraph (c) to read as follows:

§ 412.525 Adjustments to the Federal prospective payment.

* * * * *

(c) *Adjustments for area wage levels.* (1) The labor portion of a long-term care hospital's Federal prospective payment is adjusted to account for geographical differences in the area wage levels using an appropriate wage index (established by CMS), which reflects the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined in accordance with the definitions set forth in § 412.503) of the hospital compared to the national average level of hospital wages and wage-related costs. The appropriate wage index that is established by CMS is updated annually. The labor portion of a long-term care hospital's Federal prospective payment is established by CMS and is updated annually.

(2) Beginning in FY 2012, any adjustments or updates to the area wage level adjustment under this paragraph (c) will be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

10. The authority citation for Part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106–133 (113 Stat. 1501A–332).

11. Section 413.70 is amended by—

a. Revising paragraph (b)(5)(i)(B).

b. Adding a new paragraph (b)(5)(i)(C).

The revision and addition read as follows:

§ 413.70 Payment for services of a CAH.

* * * * *

(b) * * *

(5) * * *

(i) * * *

(B) Effective for cost reporting periods beginning on or after January 1, 2004 and on or before September 30, 2011, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity.

(C) Effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. If there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH.

* * * * *

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

12. The authority citation for Part 476 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

13. Section 476.78 is amended by—

a. In paragraph (a), removing the reference "§ 466.71" and adding in its place the reference "§ 476.71".

b. Revising paragraph (b).

The revision reads as follows:

§ 476.78 Responsibilities of health care facilities.

* * * * *

(b) *Cooperation with QIOs.* Health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO review.

(1) Providers must allocate adequate space to the QIO for its conduct of review at the times the QIO is conducting review.

(2) Providers must provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. QIOs pay providers paid under the prospective payment system for the costs of photocopying records requested by the QIO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first class postage for mailing the records to the QIO. When the QIO does postadmission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis. Providers must—

(i) Photocopy and deliver to the QIO all required information within 30 calendar days of a request;

(ii) Deliver all required medical information to the QIO within 21 calendar days from the date of the request in those situations where a potential "serious reportable event" has been identified or where other circumstances as deemed by the QIO warrant earlier receipt of all required medical information. For purposes of this paragraph, a serious reportable event is defined as a preventable, serious, and unambiguous adverse event that should never occur.

(3) Providers must inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to QIO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under § 405.332(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the provider has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the QIO within 3 working days.

(5) Providers must assure, in accordance with the provisions of their agreements with the QIO, that each case subject to preadmission review has been reviewed and approved by the QIO before admission to the hospital or a timely request has been made for QIO review.

(6)(i) Providers must agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the QIO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a provider, in accordance with its agreement with a QIO, makes a timely request for preadmission review and the QIO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Hospitals must agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the QIO.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance)

Dated: April 7, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 15, 2011.

Kathleen Sebelius,

Secretary.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Proposed Schedule of Standardized Amounts, Update Factors, and Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2011

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2012 for acute care hospitals. We also are setting forth the proposed rate-of-increase percentages for updating the target amounts for certain hospitals excluded from the IPPS for FY 2012. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are proposing the rate-of-increase percentages for updating the target amounts for certain hospitals excluded from the IPPS that are effective for cost reporting periods beginning on or after October 1, 2011.

In addition, we are setting forth a description of the methods and data we used to determine the proposed standard Federal rate that will be applicable to Medicare LTCHs for FY 2012.

In general, except for SCHs, MDHs, and hospitals located in Puerto Rico, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on the FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically have been paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Pub. L. 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Section 3124(a) of the Affordable Care Act amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to extend the MDH program and payment methodology from the end of FY 2011 to the end of FY 2012, by striking "October 1, 2011" and inserting "October 1, 2012". Section 3124(b) of the Affordable Care Act also made conforming amendments to sections 1886(b)(3)(D) and 1886(b)(3)(D)(iv) of the Act. Section 3124(b)(2) of the Affordable Care Act also amended section 13501(e)(2) of OBRA 1993 to extend the provision permitting hospitals to decline reclassification as an MDH through FY 2012. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital-specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor.

For hospitals located in Puerto Rico, the payment per discharge is based on the sum of 25 percent of an updated Puerto Rico-specific rate based on average costs per case of Puerto Rico hospitals for the base year and 75 percent of the Federal national rate. (We refer readers to section II.D.3. of this Addendum for a complete description.)

As discussed below in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2012. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2012. In section IV. of this Addendum, we are setting forth our proposed changes for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2012. In section V. of this Addendum, we are proposing to make changes in the determination of the standard Federal rate for LTCHs under the LTCH PPS for FY 2012. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the Internet.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2012

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal

years is set forth at § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth at §§ 412.211 and 412.212. Below we discuss the factors used for determining the proposed prospective payment rates for FY 2012.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the Internet) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts and Puerto Rico-specific standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act.
- Proposed updates of 1.5 percent for all areas (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for multifactor productivity and less 0.1 percentage point), as required by section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and10319(a) of the Affordable Care Act. For hospitals that fail to submit data, in a form and manner, and at the time, specified by the Secretary relating to the quality of inpatient care furnished by the hospital, pursuant to section 1886(b)(3)(B)(viii) of the Act, the proposed update is −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 1.2 percentage points for multifactor productivity, and less 0.1 percentage point).
- A proposed update of 1.5 percent to the Puerto Rico-specific standardized amount (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for multifactor productivity and less 0.1 percentage point), in accordance with section 1886(d)(9)(C)(i) of the Act, as amended by section 401(c) of Public Law 108–173, which sets the update to the Puerto Rico-specific standardized amount equal to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act.
- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index changes are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act. We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62 percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for in section 1886(d)(8)(D) of the Act, by removing the FY 2011 budget neutrality factor and applying a revised factor.
- An adjustment to ensure the effects of the rural community hospital demonstration required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration for an additional 5 years are budget neutral, as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment in light of the court's decision in *Cape Cod* v. *Sebelius* (630 F.3d 203 (D.C. Cir. 2011)).
- An adjustment to remove the FY 2011 outlier offset and apply an offset for FY 2012, as provided for in section 1886(d)(3)(B) of the Act.
- As discussed below and in section II.D. of the preamble to this proposed rule, an adjustment to meet the requirements of sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110–90 to adjust the standardized amounts to offset the estimated amount of the increase in aggregate payments (including interest) due to the effect of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 and FY 2009.

Beginning in FY 2008, we applied the budget neutrality adjustment for the rural floor to the hospital wage indices rather than the standardized amount. As we did for FY 2011, for FY 2012, we are proposing to continue to apply the rural floor budget neutrality adjustment to hospital wage indices rather than the standardized amount. Consistent with section 3141 of the Affordable Care Act, instead of applying a State level rural floor budget neutrality adjustment on the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the FY 2012 wage index for the rural floor. We note that, as proposed in section III.F.2 of the preamble of this proposed rule, we are not proposing to extend the imputed floor as this policy is set to expire with the FY 2011 wage index. Thus, the imputed floor is not reflected in the proposed FY 2012 wage index.

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. For Puerto Rico hospitals, the Puerto Rico-specific standardized amount is based on per discharge averages of adjusted target amounts from a base period (section 1886(d)(9)(B)(i) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d)(9) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS. The September 1, 1987 final rule (52 FR 33043 and 33066) contains a detailed explanation of how the target amounts were determined and how they are used in computing the Puerto Rico rates.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

In accordance with section 1886(d)(3)(E) of the Act, the Secretary estimates, from time-to-time, the proportion of hospitals' costs that are attributable to wages and wage-related costs. In general, the standardized amount is divided into labor-related and nonlabor-related amounts; only the proportion considered to be the labor-related amount is adjusted by the wage index. Section 1886(d)(3)(E) of the Act requires that 62 percent of the standardized amount be adjusted by the wage index, unless doing so would result in lower payments to a hospital than would otherwise be made. (Section 1886(d)(9)(C)(iv)(II) of the Act extends this provision to the labor-related share for hospitals located in Puerto Rico.)

For FY 2012, we are proposing to continue to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2011, for the national standardized amounts and 62.1 percent for the Puerto Rico-specific standardized amount. Consistent with section 1886(d)(3)(E) of the Act, we are applying the wage index to a labor-related share of 62 percent for all IPPS hospitals whose wage index values are less than or equal to 1.0000. For all IPPS hospitals whose wage indices are greater than 1.0000, we are applying the wage index to a labor-related share of 68.8 percent of the national standardized amount. For FY 2012, all Puerto Rico hospitals have a wage index less than 1.0. Therefore, the national labor-related share will always be 62 percent because the wage index for all Puerto Rico hospitals is less than 1.0.

For hospitals located in Puerto Rico, we are applying a labor-related share of 62.1 percent if its Puerto Rico-specific wage index is greater than 1.0000. For hospitals located in Puerto Rico whose Puerto-Rico specific wage index values are less than or equal to 1.0000, we are applying a labor share of 62 percent.

The proposed standardized amounts for operating costs appear in Table 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the Internet.

2. Computing the Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Section 1886(d)(9)(A)(ii)(II) of the Act equalizes the Puerto Rico-specific urban and rural area rates. Accordingly, we are proposing to calculate the FY 2012 national and Puerto Rico standardized amounts

irrespective of whether a hospital is located in an urban or rural location.

3. Updating the Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. As discussed in section IV.K.3. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2012 applicable percentage increase (which is based on the first quarter 2011 forecast of the FY 2006-based IPPS market basket) by the multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.2 percent, which is calculated based on IHS Global Insight, Inc.'s (IGI's) first quarter 2011 forecast. In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are proposing to further update the standardized amount for FY 2012 by the estimated market basket percentage increase less 0.1 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of Act, as added and amended by sections 3401(a) and 10319(a) of the Affordable Care Act, further state that these adjustments may result in the applicable percentage increase being less than zero. The percentage increase in the market basket reflects the average change in the price of goods and services comprising routine, ancillary, and special care unit hospital inpatient services. Based on IGI's 2011 first quarter forecast of the hospital market basket increase (as discussed in Appendix B of this proposed rule), the most recent forecast of the hospital market basket increase for FY 2012 is 2.8 percent. Thus, for FY 2012, the proposed update to the average standardized amount is 1.5 percent for hospitals in all areas (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for multifactor productivity and less 0.1 percentage point). For hospitals that do not submit quality data pursuant to section 1886(b)(3)(B)(viii), the estimated update to the operating standardized amount is −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent, less 2.0 percentage points for failure to submit data under the IQR program, less an adjustment of 1.2 percentage points for multifactor productivity, and less 0.1 percentage point). The proposed standardized amounts in Tables 1A through 1C that are published in section VI. of this Addendum and available via the Internet reflect these differential amounts.

Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.5 percent.

Although the update factors for FY 2012 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2012 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our proposed recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this proposed rule.

4. Other Adjustments to the Average Standardized Amount

As in the past, we are proposing to adjust the FY 2012 standardized amount to remove the effects of the FY 2011 geographic reclassifications and outlier payments before applying the FY 2012 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2012 payment policies.

We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to DRG classifications, recalibration of the DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

Consistent with our methodology established in the FY 2011 IPPS/LTCH final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total "operating DRG payments," which does not include IME and DSH payments. In order to account for these Medicare Advantage IME payments in determining the budget neutrality adjustments for this final rule, we identified Medicare Advantage claims from IPPS teaching hospitals in the MedPAR data. Consistent with our methodology established in the FY 2011 IPPS/LTCH final rule (75 FR 50422–50423), we first searched the MedPAR file for all claims with an IME payment greater than zero. We then filtered these claims for a subset of claims with a GHO Paid indicator with a value of "1" or if the IME payment field was equal to the DRG payment field. The GHO Paid indicator with a value of "1" in the MedPAR file indicates that the claim was paid by a Medicare Advantage plan (other than the IPPS IME payment specified at § 412.105(g)). For these Medicare Advantage claims from IPPS teaching hospitals, we computed a transfer-adjusted CMI by provider based on the FY 2011 MS–DRG GROUPER Version 28.0 assignment and relative weights. We also computed a transfer-adjusted CMI for these Medicare Advantage claims from IPPS teaching hospitals based on the proposed FY 2012 MS–DRG GROUPER Version 29.0 assignments and relative weights. These transfer-adjusted CMIs (and corresponding case counts) were used to calculate an IME teaching add-on payment in accordance with § 412.105(g). The total Medicare Advantage IME payment amount was then added to the total Federal payment amount for each provider (where applicable) in order to account for the Medicare Advantage IME payment in determining the budget neutrality adjustments. We note that we did not include Medicare Advantage IME claims when estimating outlier payments for providers because Medicare Advantage claims are not eligible for outlier payments under the IPPS.

Additionally, consistent with our methodology established in the FY 2011 IPPS/LTCH final rule (75 FR 50422–50423), we examined the MedPAR and removed pharmacy charges for antihemophilic blood factor (which are paid separately under the IPPS) with an indicator of "3" for blood clotting with a revenue code of "0636"from the covered charge field for the budget neutrality adjustments. We also removed organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.

a. Proposed Recalibration of DRG Weights and Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II. of the preamble of this proposed rule, we normalized the recalibrated DRG weights by an adjustment factor so that the average case weight after recalibration is equal to the average case weight prior to recalibration. However, equating the average case weight after recalibration to the average case weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals

because payments to hospitals are affected by factors other than average case weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with indices less than or equal to 1.0 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2012, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.C. of the preamble of this proposed rule.

For FY 2012, to comply with the requirement that DRG reclassification and recalibration of the relative weights be budget neutral for the Puerto Rico standardized amount and the hospital-specific rates, we used FY 2010 discharge data to simulate payments and compared aggregate payments using the FY 2011 labor-related share percentages, the FY 2011 relative weights, and the FY 2011 pre-reclassified wage data to aggregate payments using the FY 2011 labor-related share percentages, the proposed FY 2012 relative weights, and the FY 2011 pre-reclassified wage data. Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.998419. As discussed in section IV. of this Addendum, we also would apply the proposed DRG reclassification and recalibration budget neutrality factor of 0.998419 to the hospital-specific rates that are to be effective for cost reporting periods beginning on or after October 1, 2011.

In order to meet the statutory requirements that we do not take into account the labor-related share of 62 percent when computing wage index budget neutrality, it was necessary to use a three-step process to comply with the requirements that DRG reclassification and recalibration of the relative weights and the updated wage index and labor-related share have no effect on aggregate payments for IPPS hospitals. We first determined a proposed DRG reclassification and recalibration budget neutrality factor of 0.998419 by using the same methodology described above to determine the proposed DRG reclassification and recalibration budget neutrality factor for the Puerto Rico standardized amount and hospital-specific rates. Secondly, to compute a budget neutrality factor for wage index and labor-related share changes, we used FY 2010 discharge data to simulate payments and compared aggregate payments using proposed FY 2012 relative weights and FY 2011 pre-reclassified wage indices, and applied the FY 2011 labor-related share of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0) to aggregate payments using the proposed FY 2012 relative weights and the proposed FY 2012 pre-reclassified wage indices, and applied the proposed labor-related share for FY 2012 of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0). In addition, we applied the proposed DRG reclassification and recalibration budget neutrality factor (derived in the first step) to the rates that were used to simulate payments for this comparison of aggregate payments from FY 2011 to FY 2012. By applying this methodology, we determined a proposed budget neutrality factor of 1.000113 for changes to the wage index. Finally, we multiplied the proposed DRG reclassification and recalibration budget neutrality factor of 0.998419 (derived in the first step) by the proposed budget neutrality factor of 1.000113 for changes to the wage index (derived in the second step) to determine the proposed DRG reclassification and recalibration and updated wage index budget neutrality factor of 0.998532.

b. Reclassified Hospitals—Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that, effective with discharges occurring on or after October 1, 1988, certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that the wage index adjustments provided under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account "in applying any budget neutrality adjustment with respect to such index" under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality factor for FY 2012, we used FY 2010 discharge data to simulate payments and compared total IPPS payments with proposed FY 2012 relative weights, FY 2012 labor-related share percentages, and proposed FY 2012 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act to total IPPS payments with proposed FY 2012 relative weights, FY 2012 labor-related share percentages, and proposed FY 2012 wage data after such reclassifications. Based on these simulations, we calculated a proposed adjustment factor of 0.991528 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2012 budget neutrality adjustment factor is applied to the standardized amount after removing the effects of the FY 2011 budget neutrality adjustment factor. We note that the proposed FY 2012 budget neutrality adjustment reflects proposed FY 2012 wage index reclassifications approved by the MGCRB or the Administrator. We note that, for this proposed rule, as discussed in section III.B. of the preamble to this proposed rule, section 3137(c) of the Affordable Care Act resulted in some additional hospitals receiving reclassifications, or some hospitals receiving reclassifications to a different area. These reclassifications are included in the calculation of reclassification budget neutrality.

c. Proposed Rural Floor Budget Neutrality Adjustment

We make an adjustment to the wage index to ensure that aggregate payments to hospitals after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) are not affected. As discussed in section III.F. of the preamble of this proposed rule, consistent with section 3141 of the Affordable Care Act, the budget neutrality adjustment for the rural and imputed floors is a national adjustment to the wage index.

As discussed in section III.F.2. of the preamble of this proposed rule, for the FY 2012 wage index, there are wage data for one new hospital in rural Puerto Rico when previously there were none. Therefore, for FY 2012, we are proposing to calculate a national rural Puerto Rico wage index (used to adjust the labor-related share of the national standardized amount for hospitals in Puerto Rico which receive 75 percent of the national standardized amount) and a rural Puerto Rico-specific wage index (which will be used to adjust the labor-related share of the Puerto Rico-specific standardized amount for hospitals in Puerto Rico which receive 25 percent of the Puerto Rico-specific standardized amount). Our calculation is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). A complete discussion on the computation of the rural Puerto Rico wage index can be found in section III.G. of the preamble of this proposed rule. In past fiscal years, when there was no rural Puerto Rico wage index, we applied the national rural floor budget neutrality wage index factor to the national wage indices used to adjust the labor-related share for the national standardized amount (including the national Puerto Rico wage indexes) but did not apply this factor to the Puerto Rico-specific wage indices. We did not apply the national rural floor budget neutrality wage index factor to

the Puerto Rico-specific wage indices (nor did we compute a Puerto Rico-specific rural floor budget neutrality wage index factor) because there were no rural hospitals in Puerto Rico. As mentioned above, for FY 2012, there is now one rural Puerto Rico hospital and, therefore, it is necessary to compute and propose a Puerto Rico-specific rural floor budget neutrality wage index factor (in addition to the national factor).

To calculate both the national and Puerto Rico-specific rural floor budget neutrality adjustment factors, we used FY 2010 discharge data and proposed FY 2012 post-reclassified national and Puerto Rico-specific wage indices to simulate IPPS payments. First, we compared the national and Puerto Rico-specific simulated payments without the national and Puerto Rico-specific rural floor applied to national and Puerto Rico-specific simulated payments with the national and Puerto Rico-specific rural floor applied to determine the proposed national rural budget neutrality adjustment factor of 0.993834 and the proposed Puerto Rico-specific budget neutrality adjustment factor of 0.989226. The proposed national adjustment was applied to the national wage indices to produce a national rural floor budget neutral wage index and the proposed Puerto Rico-specific adjustment was then applied to the Puerto Rico-specific wage indices to produce a Puerto Rico-specific rural floor budget neutral wage index.

d. Proposed Adjustment in Light of Court Decision in *Cape Cod* v. *Sebelius*

We are proposing a 1.1 percent adjustment to the standardized amount in recognition of the decision of *Cape Cod* v. *Sebelius* (630 F.3d 203 (D.C. Cir. 2011)), (here after referred to as "*Cape Cod*"). However, we emphasize that remand proceedings in that case are not complete and this proposal reflects the timing of the development of this proposed rule and not a final decision as to how the remand will proceed. In *Cape Cod,* the plaintiff hospitals challenged the rural floor budget neutrality adjustments for FY 2007 and FY 2008. In its opinion, the D.C. Circuit Court found that section 4410 of the Balanced Budget Act of 1997 (BBA) Public Law 105–33, which authorized both the rural floor and rural floor budget neutrality, would not permit CMS to ignore prior year errors in calculating rural floor budget neutrality adjustments. The case has now been remanded to CMS for further proceedings consistent with the DC Circuit Court's opinion.

While *Cape Cod* involved only FYs 2007 and 2008, the decision may have implications for FY 2012 payment rates, depending on the ultimate result of the remand proceedings. In light of that opinion and the timing of the rulemaking development process, we are proposing to restore to the FY 2012 standardized amount the offset for the rural floor and imputed floor on the standardized amount over FY 1998 through 2006. By making this proposal for FY 2012, all affected parties will have an opportunity to consider and comment on this proposed adjustment. Given that the court has remanded the case to the Secretary for FYs 2007 and 2008 and those remand proceedings are not yet complete, we may decide to take a different approach in the final rule, depending on public comments or developments in the remand proceedings.

To assess the overall impact of applying the rural floor budget neutrality adjustment to the standardized amount for the years between FY 1998 and FY 2006, we remodeled the recalibration/wage index budget neutrality factor for the years at issue (for which data were available), excluding the effect of the rural floor adjustment. For example, to compute the revised recalibration/wage index budget neutrality factor for FY 2000, we compared the FY 1999 pre-reclassified wage data with no rural floor to FY 2000 pre-reclassified wage data with no rural floor. We then compared the revised factor to the wage/recalibration budget neutrality factor derived under the original modeling logic; that is, where the current year's pre-reclassified wage data had a rural floor applied. The percent change in these two factors was then calculated for each remodeled year.

Remodeled years from FY 1998 to FY 2004 showed an approximate 0.1 percentage point increase between the factors for each year. This increase results in a total 0.7 percentage points, which, based on the court's comments, we believe should be returned to the standardized amount. Beginning with FY 2005 through FY 2006, the number of States for which a floor wage index was available was extended via the imputed floor policy. With additional States receiving increases in payment due to the application of the imputed floor, we estimated the combined effects of the rural and imputed floor to be approximately 0.2 percentage points per year. This resulted in a total of 0.4 percentage points, which we believe should be returned to the standardized amount. Therefore, to remove the effects of the rural floor from the standardized amount for FY 1998 through FY 2006, we are proposing to apply a onetime adjustment of 1.1 percentage points, which would increase the standardized amount (0.7 percentage points plus 0.4 percentage points for a factor of 1.011). We note that, in the FY 2008 IPPS final rule with comment period, we applied a onetime adjustment of 1.002214 to the FY 2008 standardized amount to address a single year transition (from FY 2007 to FY 2008) to a noncumulative system of the rural floor budget neutrality adjustment. This adjustment of 1.002214 to the FY 2008 standardized amount reflected the increase to the rates to remove the effects of the rural floor budget neutrality adjustment from FY 2007. Because this 1.002214 factor remains on the rate, we are not including an adjustment for FY 2007 in our calculation above.

e. Proposed Case-Mix Budget Neutrality Adjustment

(1) Proposed Adjustment to the FY 2012 IPPS Standardized Amount for the Prospective Adjustment for FY 2010 and Subsequent Years Authorized by Section 7(b)(1)(A) of Public Law 110–90 and Section 1886(d)(3)(A)(vi) of the Act

As stated earlier, beginning in FY 2008, we adopted the MS–DRG patient classification system for the IPPS to better recognize patients' severity of illness in Medicare payment rates. In the FY 2008 IPPS final rule with comment period (73 FR 47175 through 47186), we indicated that we believe the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for changes in documentation and coding. In that final rule, using the Secretary's authority under section 1886(d)(3)(A)(vi) of the Act to maintain budget neutrality by adjusting the national standardized amounts to eliminate the effect of changes in documentation and coding that do not reflect real change in case-mix, we established prospective documentation and coding adjustments of −1.2 percent for FY 2008, −1.8 percent for FY 2009, and −1.8 percent for FY 2010 (for a total adjustment of −4.8 percent). On September 29, 2007, Public Law 110–90 was enacted. Section 7 of Public Law 110–90 included a provision that reduces the documentation and coding adjustment for the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percent for FY 2008 and −0.9 percent for FY 2009. To comply with the provision of section 7(a) of Public Law 110–90, in a final rule that appeared in the **Federal Register** on November 27, 2007 (72 FR 66886), we changed the IPPS documentation and coding adjustment for FY 2008 to −0.6 percent, and revised the FY 2008 national standardized amounts (as well as other payment factors and thresholds) accordingly, with these revisions being effective as of October 1, 2007. For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent instead of the −1.8 percent adjustment specified in the FY 2008 IPPS final rule with comment period. As required by statute, we applied a documentation and coding adjustment of −0.9 percent to the FY 2009 IPPS national standardized amounts. The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period are cumulative. As a result, the −0.9 percent documentation and coding adjustment in FY 2009 was in addition to the −0.6 percent adjustment in FY 2008, yielding a combined effect of −1.5 percent.

In the FY 2010 IPPS proposed and final rules (74 FR 24092 through 24101 and 43768 through 43772), we discussed our analysis of FY 2008 claims data and did not apply any additional documentation and coding adjustments to the average standardized amounts under section 1886(d) of the Act. We refer readers to these rules for a detailed description of our analysis, responses to comments, and final policy respectively. After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 1.054. After accounting for the −0.6 percent and the −0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. Therefore, an additional cumulative adjustment of −3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Pub. L. 110–90 to make an adjustment to the average

standardized amounts in order to eliminate the full effect of the documentation and coding changes on future payments. As we discussed in the FY 2011 IPPS/LTCH PPS final rule, we did not propose a prospective adjustment under section 7(b)(1)(A) of Public Law 110–90 for FY 2011 (75 FR 23868 through 23870). We note that, as a result, payments in FY 2011 (and in each future year until we implement the requisite adjustment) were 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90. Our actuaries estimate that this 3.9 percentage point increase will result in an aggregate payment of approximately $4 billion. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a detailed description of our analysis, responses to comments, and final policy (75 FR 50057 through 50073).

Because further delay of this prospective adjustment will result in a continued accrual of unrecoverable overpayments, we consider it imperative that CMS propose a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we are proposing a −3.15 percent prospective adjustment to the standardized amount to partially eliminate the full effect of the documentation and coding changes on future payments. Due to the offsetting nature of the remaining recoupment adjustment under section 7(b)(1)(B) of Public Law 110–90 (described below), and after considering other positive payment adjustments to FY 2012 rates proposed elsewhere in this proposed rule, we believe that the proposed −3.15 percent adjustment would allow for a significant reduction in potential unrecoverable overpayments, yet will maintain a comparable adjustment level between FY 2011 and FY 2012, reflecting the applicable percentage increase with a documentation and coding adjustment. This proposal recognized that an additional adjustment of −0.75 percent (3.9 minus 3.15) will be required in future rulemaking to complete the statutory requirement under section 7(b)(1)(A) of Public Law 110–90. At this time, we are not proposing a timeline to implement the remainder of this adjustment. We refer the reader to section II.D. of the preamble of this proposed rule for more discussion. In addition, for a complete discussion on our proposed documentation and coding adjustment to the hospital-specific rates, we refer readers to section II.D.2.c. of this Addendum.

(2) Proposed Adjustment to the FY 2012 IPPS Standardized Amount for the Recoupment or Repayment Adjustment for FY 2010 Authorized by Section 7(b)(1)(B) of Public Law 110–90

As indicated in section II.D.4. in the preamble to this proposed rule, the change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 and FY 2009 exceeded the −0.6 and −0.9 percent prospective documentation and coding adjustment applied under section 7(a) of Public Law 110–90 for those 2 years respectively by 1.9 percentage points in FY 2008 and 3.9 percentage points in FY 2009. In total, this change exceeded the cumulative prospective adjustments by 5.8 percentage points. Our actuaries estimated that this 5.8 percentage point increase resulted in an increase in aggregate payments of approximately $6.9 billion. In the FY 2011 IPPS/LTCH PPS final rule, we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012, subject to actuarial adjustment to reflect accumulated interest, would be necessary in order to meet the requirements of section 7(b)(1)(B) of Public Law 110–90 to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009.

It is often our practice to phase in rate adjustments over more than one year in order to moderate the effect on rates in any one year. Therefore, as we specified in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50425), we made an adjustment in FY 2011 to the standardized amount of −2.9 percent, representing half of the aggregate adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. As we have previously noted, unlike the prospective adjustment to the standardized amounts under section 7(b)(1)(A) of Public Law 110–90 described earlier, the recoupment or repayment adjustment to the standardized amounts under section 7(b)(1)(B) of Public Law 110–90 is not cumulative, but would be removed for subsequent fiscal years once we have offset the increase in aggregate payments for discharges for FY 2008 expenditures and FY 2009 expenditures. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a detailed description of our analysis, responses to comments, and final policy (75 FR 50057 through 50073).

While we stated in the FY 2011 IPPS/LTCH PPS final rule the need to potentially adjust the remaining −2.9 percent estimate to account for accumulated interest, our actuaries have determined that there has been no significant interest accumulation and that no additional adjustment will be required. Therefore, we are proposing to complete the recoupment adjustment according to the timeframes set forth by section 7(b)(1)(B) of Public Law 110–90 by implementing the remaining −2.9 percent adjustment, in addition to removing the effect of the −2.9 percent adjustment to the standardized amount finalized in FY 2011. Because these adjustments will, in effect, balance out, there will be no year-to-year change in the standardized amount due to this recoupment adjustment. As this adjustment will complete the required recoupment for overpayments due to documentation and coding effects on discharges occurring in FYs 2008 and 2009, we anticipate removing the effect of this adjustment by adding 2.9 percent to the standardized amount in FY 2013. We continue to believe that this is a reasonable and fair approach that satisfies the requirements of the statute while substantially moderating the financial impact on hospitals. We refer the reader to section II.D. of the preamble to this proposed rule for more discussion.

(3) Proposed Adjustment to the FY 2012 Puerto Rico Standardized Amount

As discussed in section II.D.9. of the preamble of this proposed rule, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), using the same methodology we applied to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals, our best estimate, based on the then most recently available data (FY 2009 claims paid through March 2010), was that for documentation and coding changes that occurred over FY 2008 and FY 2009, a cumulative adjustment of −2.6 percent was required to eliminate the full effect of the documentation and coding changes on future payments from the Puerto Rico-specific rate. In FY 2011, as finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), we applied an adjustment of −2.6 percent to the Puerto Rico-specific rate. Therefore, because the Puerto Rico-specific rate received a full prospective adjustment of −2.6 percent in FY 2011, we are proposing no further adjustment in this proposed rule for FY 2012. For a complete discussion on this proposal, we refer readers to section II.D.9. of the preamble of this proposed rule.

f. Rural Community Hospital Demonstration Program Adjustment

As discussed in section IV.N. of the preamble to this proposed rule, section 410A of Public Law 108–173 originally required the Secretary to establish a demonstration that modifies reimbursement for inpatient services for up to 15 small rural hospitals. Section 410A(c)(2) of Public Law 108–173 requires that "[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented."

Sections 3123 and 10313 of the Affordable Care Act extended the demonstration for an additional 5-year period, and allow up to 30 hospitals to participate in 20 States with low population densities determined by the Secretary. (In determining which States to include in the expansion, the Secretary is required to use the same criteria and data that the Secretary used to determine the States for purposes of the initial 5-year period.) In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50426), in order to achieve budget neutrality, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration as described in section IV.K. of that final rule. In other words, we applied budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration, consistent with past practice. We stated that we believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that "aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration * * * was not implemented," but does not identify the range across which aggregate payments must be held equal.

For FY 2012, we are proposing the estimated amount for the adjustment to the national IPPS rates for FY 2012 to be $52,642,213. Accordingly, to account for the estimated costs of the demonstration for the specific time periods as explained in detail in section IV.N. of the preamble of this proposed rule, for FY 2012, we computed a proposed factor of 0.999479 for the rural community hospital demonstration program budget neutrality adjustment that would be applied to the IPPS standardized rate.

We note that because the settlement process for the demonstration hospitals' third and fourth year cost reports, that is, for cost reporting periods starting in FYs 2007 and 2008, has experienced a delay, for this proposed rule, we are unable to state the costs of the demonstration corresponding to FYs 2007 and 2008 for purposes of determining the amount by which the costs of the demonstration corresponding to FYs 2007 and 2008 exceeded the amount offset by the budget neutrality adjustments for FYs and 2008. As a result, we are unable to propose the specific numeric adjustment representing this offsetting process that would be a component of the budget neutrality adjustment and that would be applied to the national IPPS rates. Therefore, the estimated budget neutrality adjustment to the national IPPS rate in this proposed rule does not include a component to account for these costs. We anticipate that this information may be available for the FY 2012 IPPS/LTCH PPS final rule, at which time, if data from settled cost reports are available, under our proposal, we would incorporate a component into the budget neutrality adjustment to the national IPPS rates to account for the amount by which the demonstration costs corresponding to FY 2007 and FY 2008 exceeded the amount offset by the budget neutrality adjustments for FYs 2007 and 2008.

g. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for "outlier" cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the "outlier threshold" or "fixed-loss" amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the outlier threshold as the outlier "fixed-loss cost threshold." To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2012 is 80 percent, the same marginal cost factor we have used since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments. We note that the statute requires outlier payments to be not less than 5 percent nor more than 6 percent of total "operating DRG payments" (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the 5.1 percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. Similarly, section 1886(d)(9)(B)(iv) of the Act requires the Secretary to reduce the average standardized amount applicable to hospitals located in Puerto Rico to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/04_outlier.asp#TopOfPage.*

(1) Proposed FY 2012 Outlier Fixed-Loss Cost Threshold

For FY 2012, we are proposing to continue to use the same methodology used for FY 2009 (73 FR 48763 through 48766) to calculate the outlier threshold. Similar to the methodology used in the FY 2009 IPPS final rule, for FY 2012, we are proposing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). As we have done in the past, to calculate the proposed FY 2012 outlier threshold, we simulated payments by applying proposed FY 2012 rates and policies using cases from the FY 2010 MedPAR files. Therefore, in order to determine the proposed FY 2012 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2010 to FY 2012.

We are proposing to continue to use a refined methodology that takes into account the lower inflation in hospital charges that are occurring as a result of the outlier final rule (68 FR 34494), which changed our methodology for determining outlier payments by implementing the use of more current CCRs. Our refined methodology uses more recent data that reflect the rate-of-change in hospital charges under the new outlier policy.

Using the most recent data available, we calculated the 1-year average annualized rate-of-change in charges per case from the last quarter of FY 2009 in combination with the first quarter of FY 2010 (July 1, 2009 through December 31, 2009) to the last quarter of FY 2010 in combination with the first quarter of FY 2011 (July 1, 2010 through December 31, 2010). This rate-of-change was 4.43 percent (1.044394) or 9.07 percent (1.090759) over 2 years. As we have done in the past, we established the proposed FY 2012 outlier threshold using hospital CCRs from the December 2010 update to the Provider-Specific File (PSF)—the most recent available data at the time of this proposed rule.

As discussed in the FY 2007 IPPS final rule (71 FR 48150), we worked with the Office of Actuary to derive the methodology described below to develop the CCR adjustment factor. For FY 2012, we are proposing to continue to use the same methodology to calculate the CCR adjustment by using the FY 2010 operating cost per discharge increase in combination with the actual FY 2010 operating market basket percentage increase determined by IHS Global Insight, Inc. (IGI), as well as the charge inflation factor described above to estimate the adjustment to the CCRs. (We note that the FY 2010 actual (otherwise referred to as "final") operating market basket percentage increase reflects historical data, whereas the published FY 2010 operating market basket update factor was based on IGI's 2009 second quarter forecast with historical data through the first quarter of 2009. We also note that while the FY 2010 published operating market basket update was based on the FY 2002-based IPPS market basket, the actual or "final" market basket percentage increase is based on the FY 2006-based IPPS market basket. Similarly, the FY 2010 published capital market basket update factor was based on the FY 2002-based capital market basket and the actual or "final" capital market basket percentage increase is based on the FY 2006-based capital market basket.) By using the operating market basket percentage increase and the increase in the average cost per discharge from hospital cost reports, we are using two different measures of cost inflation. For FY 2012, we determined the adjustment by taking the percentage increase in the operating costs per discharge from FY 2008 to FY 2009 (1.0285) from the cost report and dividing it by the final operating market basket percentage increase from FY 2009 (1.0260). This operation removes the measure of pure price increase (the market basket) from the percentage increase in operating cost per discharge, leaving the nonprice factors in the cost increase (for example, quantity and changes in the mix of goods and services). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the operating market basket percentage increase and the increase in cost per case from the cost report (the FY 2006 to FY 2007 percentage increase of operating costs per discharge of 1.0465 divided by the FY 2007 final operating market basket percentage increase of 1.036, the FY 2007 to FY 2008 percentage increase of operating costs per discharge of 1.0506 divided by FY 2008 final operating market basket percentage increase of 1.040). For FY 2012, we averaged the differentials calculated for FY 2007, FY 2008, and FY 2009, which resulted in a mean ratio of 1.0076. We multiplied the 3-year average of 1.0076 by the FY 2010 final operating market basket percentage increase of 1.021, which resulted in an operating cost inflation factor of 2.87 percent or 1.028747. We then divided the operating cost inflation factor by the 1-year average change in charges (1.044394) and applied an adjustment factor of 0.985018 to the operating CCRs from the

PSF (calculation performed on unrounded numbers).

As stated in the FY 2009 IPPS final rule (73 FR 48763), we continue to believe it is appropriate to apply only a 1-year adjustment factor to the CCRs. On average, it takes approximately 9 months for a fiscal intermediary or MAC to tentatively settle a cost report from the fiscal year end of a hospital's cost reporting period. The average "age" of hospitals' CCRs from the time the fiscal intermediary or the MAC inserts the CCR in the PSF until the beginning of FY 2009 is approximately 1 year. Therefore, as stated above, we believe a 1-year adjustment factor to the CCRs is appropriate.

We used the same methodology for the capital CCRs and determined the adjustment by taking the percentage increase in the capital costs per discharge from FY 2008 to FY 2009 (1.0508) from the cost report and dividing it by the final capital market basket percentage increase from FY 2009 (1.015). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the capital market basket percentage increase and the increase in cost per case from the cost report (the FY 2006 to FY 2007 percentage increase of capital costs per discharge of 1.0507 divided by the FY 2007 final capital market basket percentage increase of 1.013, the FY 2007 to FY 2008 percentage increase of capital costs per discharge of 1.0811 divided by the FY 2008 final capital market basket percentage increase of 1.015). For FY 2012, we averaged the differentials calculated for FY 2007, FY 2008, and FY 2009, which resulted in a mean ratio of 1.0459. We multiplied the 3-year average of 1.0459 by the FY 2010 final capital market basket percentage increase of 1.010, which resulted in a capital cost inflation factor of 5.63 percent or 1.056329. We then divided the capital cost inflation factor by the 1-year average change in charges (1.044394) and applied an adjustment factor of 1.011428 to the capital CCRs from the PSF (calculation performed on unrounded numbers). We are proposing to use the same charge inflation factor for the capital CCRs that was used for the operating CCRs. The charge inflation factor is based on the overall billed charges. Therefore, we believe it is appropriate to apply the charge factor to both the operating and capital CCRs.

As stated above, for FY 2012, we applied the proposed FY 2012 rates and policies using cases from the FY 2010 MedPAR files in calculating the proposed outlier threshold. As discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.F. of this proposed rule, in accordance with section 10324(a) of the Affordable Care Act, beginning in FY 2011, we created a wage index floor of 1.00 for all hospitals located in States determined to be frontier States. We noted that the frontier State floor adjustments will be calculated and applied after rural and imputed floor budget neutrality adjustments are calculated for all labor market areas, in order to ensure that no hospital in a frontier State will receive a wage index lesser than 1.00 due to the rural and imputed floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the proposed outlier threshold for FY 2012, it was necessary to apply this provision by adjusting the wage index of those eligible hospitals in a frontier State when calculating the outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2012. If we did not take into account this provision, our estimate of total FY 2012 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments.

For this proposed rule, we are using the FY 2010 claims data to calculate the FY 2012 proposed outlier threshold. Our estimate of the cumulative effect of changes in documentation and coding due to the adoption of the MS–DRGs through FY 2010 is 5.4 percent, which is already included within the claims data (FY 2010 MedPAR files) used to calculate the proposed FY 2012 outlier threshold. Furthermore, we currently estimate that there would be no continued changes in documentation and coding in FYs 2011 and 2012. Therefore, the cumulative effect of documentation and coding that has occurred is already reflected within the FY 2010 MedPAR claims data, and we do not believe there is any need to inflate FY 2010 claims data for any additional case-mix growth projected to have occurred since FY 2010.

Using this methodology, we are proposing an outlier fixed-loss cost threshold for FY 2012 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $23,375.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2012 outlier payments, we are not proposing to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 outlier final rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We also note that reconciliation occurs because hospitals' actual CCRs for the cost reporting period are different than the interim CCRs used to calculate outlier payments when a bill is processed. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we are proposing not to make any assumptions about the effects of reconciliation on the outlier threshold calculation.

(2) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2012 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 5.93 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are proposing to reduce the FY 2012 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that would be applied to the standardized amount based on the proposed FY 2012 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate
National	0.949000	0.940626
Puerto Rico	0.955896	0.929936

We are proposing to apply the outlier adjustment factors to the proposed FY 2012 rates after removing the effects of the FY 2011 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, for hospitals for which the fiscal intermediary or MAC computes operating CCRs greater than 1.147 or capital CCRs greater than 0.158, or hospitals for which the fiscal intermediary or MAC is unable to calculate a CCR (as described at § 412.84(i)(3) of our regulations),

we use statewide average CCRs to determine whether a hospital qualifies for outlier payments.[61] Table 8A listed in section VI. of this Addendum (and available only via the Internet) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the fiscal intermediary or MAC is unable to compute a hospital-specific CCR within the above range. Effective for discharges occurring on or after October 1, 2011, these statewide average ratios would replace the ratios published in the IPPS final rule for FY 2011 (75 FR 50390–50392). Table 8B listed in section VI. of this Addendum (and available via the Internet) contains the proposed comparable statewide average capital CCRs. Again, the proposed CCRs in Tables 8A and 8B would be used during FY 2012 when hospital-specific CCRs based on the latest settled cost report are either not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the Internet) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their fiscal intermediary or MAC on a possible alternative operating and/or capital CCR as explained in Change Request 3966. Use of an alternative CCR developed by the hospital in conjunction with the fiscal intermediary or MAC can avoid possible overpayments or underpayments at cost report settlement, thus ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR ratio at any time as long as the guidelines of Change Request 3966 are followed. Additionally, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010 which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.*

(3) FY 2010 and FY 2011 Outlier Payments

In the FY 2011 IPPS final rule (75 FR 50431), we stated that, based on available data, we estimated that actual FY 2010 outlier payments would be approximately 4.7 percent of actual total DRG payments. This estimate was computed based on simulations using the FY 2009 MedPAR file (discharge data for FY 2009 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2010 claims, but instead reflected the application of FY 2010 rates and policies to available FY 2009 claims.

Our current estimate, using available FY 2010 claims data, is that actual outlier payments for FY 2010 were approximately 4.7 percent of actual total DRG payments. Thus, the data indicate that, for FY 2010, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 2010. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not plan to make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2010 are equal to 5.1 percent of total DRG payments.

We currently estimate that actual outlier payments for FY 2011 will be approximately 4.9 percent of actual total DRG payments, approximately 0.2 percentage points lower than the 5.1 percent we projected when setting the outlier policies for FY 2011. This estimate of 4.9 percent is based on simulations using the FY 2010 MedPAR file (discharge data for FY 2010 claims).

5. Proposed FY 2012 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the Internet) contain the national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2012. The proposed Puerto Rico-specific amounts are shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is the labor-related share of 68.8 percent, and Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are applying a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals (other than those in Puerto Rico) whose wage indices are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increase of 1.5 percent for FY 2012, and a proposed update of −0.5 percent for hospitals that fail to submit quality data consistent with section 1886(b)(3)(B)(viii) of the Act.

Under section 1886(d)(9)(A)(ii) of the Act, the Federal portion of the Puerto Rico payment rate is based on the discharge-weighted average of the national large urban standardized amount (this amount is set forth in Table 1A). The labor-related and nonlabor-related portions of the proposed national average standardized amounts for Puerto Rico hospitals for FY 2011 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). This table also includes the proposed Puerto Rico standardized amounts. The labor-related share applied to the Puerto Rico specific standardized amount is the labor-related share of 62.1 percent, or 62 percent, depending on which provides higher payments to the hospital. (Section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.)

The following table illustrates the proposed changes from the FY 2011 national standardized amount. The second column shows the proposed changes from the FY 2011 standardized amounts for hospitals that satisfy the quality data submission requirement and therefore receive the full update of 1.5 percent. The third column shows the proposed changes for hospitals receiving the reduced update of −0.5 percent. The first row of the table shows the proposed updated (through FY 2011) average standardized amount after restoring the FY 2011 offsets for outlier payments, demonstration budget neutrality and the geographic reclassification budget neutrality. The DRG reclassification and recalibration wage index budget neutrality factors are cumulative. Therefore, the FY 2011 factor is not removed from this table.

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[61] These figures represent 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals.

COMPARISON OF FY 2011 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2012 STANDARDIZED AMOUNT WITH FULL AND REDUCED UPDATE

	Full Update (1.5 percent); Wage index is greater than 1.0000	Full Update (1.5 percent); Wage index is less than or equal to 1.0000	Reduced Update (-0.5 percent); Wage index is greater than 1.0000	Reduced Update (-0.5 percent); Wage index is less than or equal to 1.0000
FY 2011 Base Rate, after removing geographic reclassification budget neutrality, demonstration budget neutrality, cumulative FY 2008 and FY 2009 documentation and coding adjustment, FY 2011 documentation and coding recoupment, and outlier offset (based on the labor-related share percentage for FY 2011)	Labor: $3,947.65 Nonlabor: $1,790.21	Labor: $3,557.48 Nonlabor: $2,180.39	Labor: $3,947.65 Nonlabor: $1,790.21	Labor: $3,557.48 Nonlabor: $2,180.39
Proposed FY 2012 Update Factor	1.015	1.015	0.9950	0.9950
Proposed Adjustment for Restoring Rural Floor Budget Neutrality	1.011	1.011	1.011	1.011
Proposed FY 2012 DRG Recalibration and Wage Index Budget Neutrality Factor	0.998532	0.998532	0.998532	0.998532
Proposed FY 2012 Reclassification Budget Neutrality Factor	0.991528	0.991528	0.991528	0.991528
Proposed FY 2012 Rural Demonstration Budget Neutrality Factor	0.999479	0.999479	0.999479	0.999479
Proposed FY 2012 Outlier Factor	0.949000	0.949000	0.949000	0.949000
Proposed documentation and coding adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110-90	0.9282	0.9282	0.9282	0.9282
Proposed Rate for FY 2012	Labor: $3,531.06 Nonlabor: $1,601.30	Labor: $3,182.06 Nonlabor:$1,950.30	Labor: $3,461.48 Nonlabor: $1,569.75	Labor: $3,119.36 Nonlabor: $1,911.87

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B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the Internet), contain the labor-related and nonlabor-related shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2012. This section addresses two types of adjustments to the standardized amounts that are made in determining the proposed prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national and Puerto Rico prospective payment rates, respectively, to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. In section III. of the preamble of this proposed rule, we discuss the data and methodology for the proposed FY 2012 wage index.

2. Proposed Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act authorizes the Secretary to make an adjustment to take into account the unique circumstances of

hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. For FY 2011 and in prior fiscal years, we used the most recent updated cost of living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) Web site at *http://www.opm.gov/oca/cola/rates.asp.* We multiply the nonlabor-related portion of the standardized amount by the applicable adjustment factor.

Sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009) transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Public Law 111–84, locality pay is being phased in over a 3-year period beginning in January 2010 with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay.

We do not believe it is appropriate to propose to use either the 2010 or 2011 reduced factors for adjusting the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii for Medicare payment purposes. Therefore, for FY 2012, we are proposing to continue to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which are based on OPMs 2009 COLA factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. We believe using these COLAs will appropriately adjust the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii consistent with section 1886(d)(5)(H) of the Act. We invite public comments on this proposal.

Below is a table of factors obtained from OPM that we are proposing for FY 2012, which are the same as the factors currently in use under the IPPS for FY 2011.

Table of Cost-of-Living Adjustment Factors: Alaska and Hawaii Hospitals

Area	Cost of Living Adjustment Factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.18
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

(The above factors are based on data obtained from the U.S. Office of Personnel Management Web site at: http://www.opm.gov/oca/cola/rates.asp.)

C. Proposed MS–DRG Relative Weights

As discussed in section II.H. of the preamble of this proposed rule, we have developed relative weights for each MS–DRG that reflect the resource utilization of cases in each MS–DRG relative to Medicare cases in other MS–DRGs. Table 5 listed in section VI. of this Addendum (and available via the Internet) contains the relative weights that we are proposing to apply to discharges occurring in FY 2012. These factors have been recalibrated as explained in section II. of the preamble of this proposed rule.

D. Calculation of the Proposed Prospective Payment Rates

General Formula for Calculation of the Proposed Prospective Payment Rates for FY 2012

In general, the operating prospective payment rate for all hospitals paid under the IPPS located outside of Puerto Rico, except SCHs and MDHs, for FY 2012 equals the Federal rate.

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on the FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2012 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for MDHs for FY 2012 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described below. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987 or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

The prospective payment rate for hospitals located in Puerto Rico for FY 2012 equals 25 percent of the Puerto Rico rate plus 75 percent of the applicable national rate.

1. Federal Rate

The Federal rate is determined as follows:

Step 1—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data (full update for hospitals submitting quality data; update including a −2.0 percent adjustment for hospitals that did not submit these data).

Step 2—Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3—For hospitals in Alaska and Hawaii, multiply the nonlabor-related

portion of the standardized amount by the applicable cost-of-living adjustment factor.

Step 4—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount (adjusted, if applicable, under Step 3).

Step 5—Multiply the final amount from Step 4 by the relative weight corresponding to the applicable MS–DRG (Table 5 listed in section VI. of this Addendum and available via the Internet).

The Federal rate as determined in Step 5 may then be further adjusted if the hospital qualifies for either the IME or DSH adjustment. In addition, for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b), the payment in Step 5 would be increased by the formula described in section IV.E. of the preamble of this proposed rule.

2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that currently SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on the FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As discussed previously, currently MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the greater of the updated hospital-specific rates based on either FY 1982, FY 1987 or FY 2002 costs per discharge.

Hospital-specific rates have been determined for each of these hospitals based on the FY 1982 costs per discharge, the FY 1987 costs per discharge, or, for SCHs, the FY 1996 costs per discharge or the FY 2006 costs per discharge, and for MDHs, the FY 2002 cost per discharge. For a more detailed discussion of the calculation of the hospital-specific rates, we refer the reader to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002, and FY 2006 Hospital-Specific Rates for FY 2012

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increase to the hospital-specific rates applicable to SCHs and MDHs is 1.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for multifactor productivity and less 0.1 percentage point) for hospitals that submit quality data or −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 1.2 percentage points for multifactor productivity, and less 0.1 percentage points) for hospitals that fail to submit quality data. For a complete discussion of the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs, we refer readers to section IV.H. of the preamble of this proposed rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the DRG classifications and the recalibration of the DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, for both SCHs and MDHs, the hospital-specific rate is adjusted by the proposed DRG reclassification and recalibration budget neutrality factor of 0.998419, as discussed in section III. of this Addendum. The resulting rate would be used in determining the payment rate an SCH or MDH will receive for its discharges beginning on or after October 1, 2011.

c. Documentation and Coding Adjustment to the FY 2012 Hospital-Specific Rates for SCHs and MDHs

As discussed in section II.D. of the preamble of this proposed rule, because hospitals (SCHs and MDHs) paid based in whole or in part on the hospital-specific rate use the same MS–DRG system as other hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patients' severity of illness. Under section 1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid based on the standardized amount should not receive additional payments based on the effect of documentation and coding changes that do not reflect real changes in case-mix. Similarly, we believe that hospitals paid based on the hospital-specific rate should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patients' severity of illness. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50426) and in section II.D. of the preamble of this proposed rule, we believe they should be equally subject to a prospective budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. While we continue to believe that section 1886(d)(3)(A)(vi) of the Act does not provide explicit authority for application of the documentation and coding adjustment to the hospital-specific rates, we believe that we have the authority to apply the documentation and coding adjustment to the hospital-specific rates using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act.

As we discuss in section II.D. of the preamble of this proposed rule, our best estimate, based on the most recently available data, is that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of the documentation and coding changes on future payments to SCHs and MDHs. Unlike the case of standardized amounts paid to IPPS hospitals, prior to FY 2011 we had not made any previous adjustments to the hospital specific rates paid to SCHs and MDHs to account for documentation and coding changes. Consequently, in order to maintain consistency as far as possible with the adjustments applied to IPPS hospitals, we made an adjustment of −2.9 percent in FY 2011 to the hospital-specific rates paid to SCHs and MDHs.

As discussed above, we are proposing a −3.15 percent documentation and coding adjustment for IPPS hospitals in FY 2012 (−3.15 percent prospective adjustment plus a −2.9 percent recoupment adjustment in FY 2012, offset by the removal of the −2.9 percent recoupment adjustment for FY 2011). The proposed IPPS documentation and coding adjustment exceeds the remaining −2.5 percent documentation and coding adjustment for hospitals receiving a hospital-specific rate (that is, the entire −5.4 percent adjustment, minus the −2.9 percent adjustment finalized for FY 2011). We believe that any adjustment to the hospital-specific rate due to documentation and coding effect should be as similar as possible to adjustments to the IPPS rate. Accordingly, we are proposing a −2.5 percent payment adjustment to the hospital-specific rate. We believe that proposing the entire remaining prospective adjustment of −2.5 percent allows CMS to maintain, to the extent possible, similarity and consistency in payment rates for different IPPS hospitals paid using the MS–DRG.

d. Proposed Adjustment to Restore Prior Rural Floor Budget Neutrality Offsets

As discussed in section II.A.4.d. of this Addendum, in light of the *Cape Cod* decision, we are proposing to adjust hospital-specific amounts by 0.9 percent to restore to these amounts the offset for the rural floor and imputed floor in prior years. Our rationale and methodology for such adjustment are explained in section II.A.4.d of this Addendum. As with the standardized amount, we are proposing to return 0.7 percentage points for FYs 1998 through 2004, and 0.2 percentage points for FY 2005 to the hospital-specific rates. We note that, in the FY 2006 IPPS final rule (70 FR 47429 and 47430), beginning in FY 2006, we changed our methodology and began applying only the DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates. Because the rural floor budget neutrality adjustment was not applied to the hospital-specific rates in FYs 2006 and 2007, we are not including FY 2006 and FY 2007

in our assessment. Therefore, to remove the effects of the rural floor from the hospital-specific rates for FYs 1998 through 2005, we are proposing to apply a onetime permanent adjustment of 0.9 percent to the hospital-specific rates (that is, a factor of 1.009).

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning on or after October 1, 2011, and before October 1, 2012

Section 1886(d)(9)(E)(iv) of the Act provides that, effective for discharges occurring on or after October 1, 2004, hospitals located in Puerto Rico are paid based on a blend of 75 percent of the national prospective payment rate and 25 percent of the Puerto Rico-specific rate.

a. Puerto Rico Rate

The Puerto Rico prospective payment rate is determined as follows:

Step 1—Select the applicable average standardized amount considering the applicable wage index (Table 1C published in section VI. of this Addendum and available via the Internet).

Step 2—Multiply the labor-related portion of the standardized amount by the applicable Puerto Rico-specific wage index.

Step 3—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount.

Step 4—Multiply the amount from Step 3 by the applicable MS–DRG relative weight (Table 5 listed in section VI. of this Addendum and available via the Internet).

Step 5—Multiply the result in Step 4 by 25 percent.

b. National Rate

The national prospective payment rate is determined as follows:

Step 1—Select the applicable average standardized amount.

Step 2—Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3—Add the amount from Step 2 and the nonlabor-related portion of the national average standardized amount.

Step 4—Multiply the amount from Step 3 by the applicable MS–DRG relative weight (Table 5 listed in section VI. of this Addendum and available via the Internet).

Step 5—Multiply the result in Step 4 by 75 percent.

The sum of the Puerto Rico rate and the national rate computed above equals the prospective payment for a given discharge for a hospital located in Puerto Rico. This rate would then be further adjusted if the hospital qualifies for either the IME or DSH adjustment.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2012

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. Effective with that cost reporting period, hospitals were paid during a 10-year transition period (which extended through FY 2001) to change the payment methodology for Medicare acute care hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. Below we discuss the factors that we used to determine the proposed capital Federal rate for FY 2012, which would be effective for discharges occurring on or after October 1, 2011.

The 10-year transition period ended with hospital cost reporting periods beginning on or after October 1, 2001 (FY 2002). Therefore, for cost reporting periods beginning in FY 2002, all hospitals (except "new" hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. For FY 1992, we computed the standard Federal payment rate for capital-related costs under the IPPS by updating the FY 1989 Medicare inpatient capital cost per case by an actuarial estimate of the increase in Medicare inpatient capital costs per case. Each year after FY 1992, we update the capital standard Federal rate, as provided at § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for (regular and special) exceptions under § 412.348. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

For FYs 1992 through 1995, § 412.352 required that the capital Federal rate also be adjusted by a budget neutrality factor so that aggregate payments for inpatient hospital capital costs were projected to equal 90 percent of the payments that would have been made for capital-related costs on a reasonable cost basis during the respective fiscal year. That provision expired in FY 1996. Section 412.308(b)(2) describes the 7.4 percent reduction to the capital Federal rate that was made in FY 1994, and § 412.308(b)(3) describes the 0.28 percent reduction to the capital Federal rate made in FY 1996 as a result of the revised policy for paying for transfers. In FY 1998, we implemented section 4402 of Public Law 105–33, which required that, for discharges occurring on or after October 1, 1997, the budget neutrality adjustment factor in effect as of September 30, 1995, be applied to the unadjusted capital standard Federal rate and the unadjusted hospital-specific rate. That factor was 0.8432, which was equivalent to a 15.68 percent reduction to the unadjusted capital payment rates. An additional 2.1 percent reduction to the rates was effective from October 1, 1997 through September 30, 2002, making the total reduction 17.78 percent. As we discussed in the FY 2003 IPPS final rule (67 FR 50102) and implemented in § 412.308(b)(6), the 2.1 percent reduction was restored to the unadjusted capital payment rates effective October 1, 2002.

To determine the appropriate budget neutrality adjustment factor and the regular exceptions payment adjustment during the 10-year transition period, we developed a dynamic model of Medicare inpatient capital-related costs; that is, a model that projected changes in Medicare inpatient capital-related costs over time. With the expiration of the budget neutrality provision, the capital cost model was only used to estimate the regular exceptions payment adjustment and other factors during the transition period. As we explained in the FY 2002 IPPS final rule (66 FR 39911), beginning in FY 2002, an adjustment for regular exception payments is no longer necessary because regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991, and before October 1, 2001 (see § 412.348(b)). Because payments are no longer made under the regular exception policy effective with cost reporting periods beginning in FY 2002, we discontinued use of the capital cost model. The capital cost model and its application during the transition period are described in Appendix B of the FY 2002 IPPS final rule (66 FR 40099).

Section 412.374 provides for blended payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. In accordance with section 1886(d)(9)(A) of the Act, under the IPPS for acute care hospital operating costs, hospitals located in Puerto Rico are paid for operating costs under a special payment formula. Prior to FY 1998, hospitals located in Puerto Rico were paid a blended operating rate that consisted of 75 percent of the applicable standardized amount specific to Puerto Rico hospitals and 25 percent of the applicable national average standardized amount. Similarly, prior to FY 1998, hospitals located in Puerto Rico were paid a blended capital rate that consisted of 75 percent of the applicable capital Puerto Rico-specific rate and 25 percent of the applicable capital Federal rate. However, effective October 1, 1997, in accordance with section 4406 of Public Law 105–33, the methodology for operating payments made to hospitals located in Puerto Rico under the IPPS was revised to make payments based on a blend of 50 percent of the applicable standardized amount specific to Puerto Rico hospitals and 50 percent of the applicable national average standardized amount. In conjunction with this change to the operating blend percentage, effective with discharges occurring on or after October 1, 1997, we also revised the methodology for computing capital payments to hospitals located in Puerto Rico to be based on a blend of 50 percent of the Puerto Rico capital rate and 50 percent of the national capital Federal rate.

As we discussed in the FY 2005 IPPS final rule (69 FR 49185), section 504 of Public Law

108–173 increased the national portion of the operating IPPS payments for hospitals located in Puerto Rico from 50 percent to 62.5 percent and decreased the Puerto Rico portion of the operating IPPS payments from 50 percent to 37.5 percent for discharges occurring on or after April 1, 2004 through September 30, 2004 (refer to the March 26, 2004 One-Time Notification (Change Request 3158)). In addition, section 504 of Public Law 108–173 provided that the national portion of operating IPPS payments for hospitals located in Puerto Rico is equal to 75 percent and the Puerto Rico-specific portion of operating IPPS payments is equal to 25 percent for discharges occurring on or after October 1, 2004. Consistent with that change in operating IPPS payments to hospitals located in Puerto Rico, for FY 2005 we revised the methodology for computing capital payments to hospitals located in Puerto Rico to be based on a blend of 25 percent of the Puerto Rico-specific capital rate and 75 percent of the national capital Federal rate for discharges occurring on or after October 1, 2004 (69 FR 49185).

A. Determination of Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the discussion that follows, we explain the factors that we used to determine the proposed capital Federal rate for FY 2012. In particular, we explain why the proposed FY 2012 capital Federal rate would increase approximately 0.60 percent, compared to the FY 2011 capital Federal rate. As discussed in the impact analysis in Appendix A of this proposed rule, we estimate that capital payments per discharge would increase 1.7 percent during that same period. Because capital payments constitute about 10 percent of hospital payments, a percent change in the capital Federal rate yields only about a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate-of-increase as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed update factor for FY 2012 under that framework is 1.5 percent based on the best data available at this time. The proposed update factor under that framework is based on a projected 1.5 percent increase in the CIPI, a 0.0 percent adjustment for intensity, a 0.0 percent adjustment for case-mix, a 0.0 percent adjustment for the FY 2010 DRG reclassification and recalibration, and a forecast error correction of 0.0 percent. As discussed below in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2012 CIPI projection in that same section of this Addendum. We note, as discussed in section VI.E.1. of the preamble of this proposed rule, we are proposing to apply a −1.0 percent adjustment to the capital rate in FY 2012 to account for the effect of changes in documentation and coding under the MS–DRGs that do not correspond to changes in real increases in patients' severity of illness. Below we describe the policy adjustments that we are proposing to apply in the update framework for FY 2012.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patients changes ("real" case-mix change);
- Changes in hospital documentation and coding of patient records result in higher weight DRG assignments ("coding effects"); and
- The annual DRG reclassification and recalibration changes may not be budget neutral ("reclassification effect").

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in documentation and coding behavior that result in assignment of cases to higher weighted DRGs but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts as discussed in section II. of Appendix B in the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2012, we are projecting a 1.0 percent total increase in the case-mix index. We estimated that the real case-mix increase would also equal 1.0 percent for FY 2012. The proposed net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, the proposed net adjustment for case-mix change in FY 2012 is 0.0 percentage points.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2010 DRG reclassification and recalibration as part of our update for FY 2012. To adjust for reclassification and recalibration effects, under our historical methodology, we would run the FY 2010 cases through the FY 2009 GROUPER and through the FY 2010 GROUPER. If the resulting ratio of the case-mix indices did not equate to 1.0, in the update framework for FY 2012, we would propose to make an adjustment to account for the reclassification and recalibration effects in FY 2010. In the update framework for FY 2011 (the FY 2011 IPPS final rule (75 FR 50435)), we did not adjust for reclassification and recalibration effects from FY 2009 because it was accounted for in the documentation and coding adjustment to the capital Federal rates for FY 2011. For FY 2012, we are proposing not to perform an analysis of changes in case-mix in FY 2010 due to the effect of documentation and coding, as this would be most consistent with our approach under the operating IPPS. Therefore, at this time, under our broad authority in section 1886(g) of the Act, we are proposing a 0.0 percent adjustment for reclassification and recalibration in the update framework. We may evaluate the effect of FY 2010 reclassification and recalibration if we perform an analysis of the documentation and coding effect in FY 2010 in future rulemaking.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. A forecast error of −0.2 percentage point was calculated for the proposed FY 2012 update. That is, current historical data indicate that the forecasted FY 2010 CIPI (1.2 percent) used in calculating the FY 2010 update factor was 0.2 percentage point higher than the actual realized price increases (1.0 percent). The two primary contributing factors for the FY 2011 CIPI forecast being slightly higher than the actual FY 2011 increase in the CIPI were that the prices for the nonprofit and government interest cost category grew slower than what had been forecasted, and the prices for the other capital expenses cost category also grew slower than what had been forecasted. Because the estimation of the change in the CIPI is not greater than 0.25 percentage point, we are proposing to make a 0.0 percent adjustment for forecast error in the update for FY 2012.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculated this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflected how hospital services are utilized to produce the final product, that is, the

discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove non-cost-effective services. Our intensity measure is based on a 5-year average.

Historically, we calculated case-mix constant intensity as the change in total charges per admission, adjusted for price level changes (the CIPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity increases that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual increase is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

We developed a Medicare-specific intensity measure based on a 5-year average. Past studies of case-mix change by the RAND Corporation (*Has DRG Creep Crept Up? Decomposing the Case Mix Index Change Between 1987 and 1988* by G. M. Carter, J. P. Newhouse, and D. A. Relles, R–4098–HCFA/ProPAC (1991)) suggest that real case-mix change was not dependent on total change, but was usually a fairly steady increase of 1.0 to 1.5 percent per year. However, we used 1.4 percent as the upper bound because the RAND study did not take into account that hospitals may have induced doctors to document medical records more completely in order to improve payment.

In accordance with § 412.308(c)(1)(ii), we began updating the capital standard Federal rate in FY 1996 using an update framework that takes into account, among other things, allowable changes in the intensity of hospital services, as noted above. For much of the last decade, we found that the charge data appeared to be skewed as a result of hospitals attempting to maximize outlier payments, while lessening costs, and we established a 0.0 percent adjustment for intensity in each of those years. Therefore, for FY 2011, in an effort to further refine the intensity adjustment and more accurately reflect allowable changes in hospital intensity, we revised our intensity measure to use changes in hospital *costs* per discharge over a 5-year average rather than changes in hospital charges, which had been the basis of the intensity adjustment in prior years. The unique nature of capital—how and when it is purchased, its longevity, and how it is financed—creates a greater degree of variance in capital cost among hospitals than does operating cost. As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436), we believe that using changes in capital costs per discharge as the basis for the intensity adjustment in lieu of changes in charges will decrease some of the variability of this adjustment. In this proposed rule, for FY 2012, we are proposing to use an intensity measure that is based on a 5-year adjusted average of cost per discharge, as we did for FY 2011. Therefore, the proposed intensity measure for FY 2012 is based on an average of cost per discharge data from the 5-year period beginning with FY 2005 and extending through FY 2009. Based on these data, we estimated that case-mix constant intensity declined during FYs 2005 through 2009. In the past, when we found intensity to be declining, we believed a zero (rather than negative) intensity adjustment was appropriate. Consistent with this approach, because we estimate that intensity declined during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2012. Therefore, we are proposing to make a 0.0 percent adjustment for intensity in the update for FY 2012.

Above, we described the basis of the components used to develop the proposed 1.5 percent capital update factor under the capital update framework for FY 2012 as shown in the table below.

Proposed CMS FY 2012 Update Factor to the Capital Federal Rate

Capital Input Price Index	1.5
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	-1.0
Projected Case-Mix Change	1.0
Subtotal	1.5
Effect of FY 2010 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.5

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2011 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2012. (MedPAC's Report to the Congress: Medicare Payment Policy, March 2011, Chapter 3.)

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments.

For FY 2011, we estimated that outlier payments for capital would equal 5.96 percent of inpatient capital-related payments based on the capital Federal rate in FY 2011. Based on the thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs will equal 5.94 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2012. Therefore, we are proposing to apply an outlier adjustment factor of 0.9406 in determining the capital Federal rate. Thus, we estimate that the percentage of capital outlier payments to total capital standard payments for FY 2012 would be slightly lower than the percentage for FY 2011. This slight decrease in estimated capital outlier payments is primarily due to the estimated increase in capital IPPS payments per discharge. That is, because capital payments per discharge are projected to be higher in FY 2012 compared to FY 2011, as shown in Table III. in section VIII. of Appendix A to this proposed rule, fewer cases would qualify for outlier payments.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in

determining the capital Federal rate. The proposed FY 2012 outlier adjustment of 0.9406 is a 0.02 percent change from the FY 2011 outlier adjustment of 0.9404. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2012 is 1.0002 (0.9406/0.9404). Thus, the proposed outlier adjustment would increase the FY 2012 capital Federal rate by 0.02 percent compared with the FY 2011 outlier adjustment.

3. Proposed Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. Because we implemented a separate GAF for Puerto Rico, we apply separate budget neutrality adjustments for the national GAF and the Puerto Rico GAF. We apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. Separate adjustments were unnecessary for FY 1998 and earlier because the GAF for Puerto Rico was implemented in FY 1998.

In the past, we used the actuarial capital cost model (described in Appendix B of the FY 2002 IPPS final rule (66 FR 40099)) to estimate the aggregate payments that would have been made on the basis of the capital Federal rate with and without changes in the DRG classifications and weights and in the GAF to compute the adjustment required to maintain budget neutrality for changes in DRG weights and in the GAF. During the transition period, the capital cost model was also used to estimate the regular exception payment adjustment factor. As we explained in section III.A. of this Addendum, beginning in FY 2002, an adjustment for regular exception payments was no longer necessary. Therefore, we no longer use the capital cost model. Furthermore, as discussed below, special exceptions payments will no longer be made in FY 2012, and an exceptions payment adjustment factor will no longer be necessary, as there are no remaining hospitals eligible to receive special exceptions payments.

To determine the proposed factors for FY 2012, we compared (separately for the national capital rate and the Puerto Rico capital rate) estimated aggregate capital Federal rate payments based on the FY 2011 MS–DRG classifications and relative weights and the FY 2011 GAF to estimated aggregate capital Federal rate payments based on the FY 2011 MS–DRG classifications and relative weights and the proposed FY 2012 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we are proposing to apply an incremental budget neutrality adjustment of 1.0005 for FY 2012 to the previous cumulative FY 2011 adjustment of 0.9902, yielding an adjustment of 0.9906, through FY 2012. For the Puerto Rico GAFs, we are proposing to apply an incremental budget neutrality adjustment of 1.0087 for FY 2012 to the previous cumulative FY 2011 adjustment of 0.9965, yielding a cumulative adjustment of 1.0052 through FY 2012.

We then compared estimated aggregate capital Federal rate payments based on the FY 2011 DRG relative weights and the proposed FY 2012 GAFs to estimate aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2012 MS–DRG classifications and relative weights and the proposed FY 2012 GAFs. The proposed incremental adjustment for DRG classifications and proposed changes in relative weights is 1.0000 both nationally and for Puerto Rico. The proposed cumulative adjustments for MS–DRG classifications and proposed changes in relative weights and for proposed changes in the GAFs through FY 2012 are 0.9906 nationally and 1.0052 for Puerto Rico. We note that all the values are calculated with unrounded numbers. The following table summarizes the adjustment factors for each fiscal year:

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PROPOSED BUDGET NEUTRALITY ADJUSTMENT FOR DRG RECLASSIFICATIONS AND RECALIBRATION AND THE GEOGRAPHIC ADJUSTMENT FACTORS

Fiscal Year	National				Puerto Rico			
	Incremental Adjustment			Cumulative	Incremental Adjustment			Cumulative
	Geographic Adjustment Factor	DRG Reclassifications and Recalibration	Combined		Geographic Adjustment Factor	DRG Reclassifications and Recalibration	Combined	
1992	—	—	—	1.00000	—	—	—	—
1993	—	—	0.99800	0.99800	—	—	—	—
1994	—	—	1.00531	1.00330	—	—	—	—
1995	—	—	0.99980	1.00310	—	—	—	—
1996	—	—	0.99940	1.00250	—	—	—	—
1997	—	—	0.99873	1.00123	—	—	—	—
1998	—	—	0.99892	1.00015	—	—	—	1.00000
1999	0.99944	1.00335	1.00279	1.00294	0.99898	1.00335	1.00233	1.00233
2000	0.99857	0.99991	0.99848	1.00142	0.99910	0.99991	0.99901	1.00134
2001[1]	0.99782	1.00009	0.99791	0.99933	1.00365	1.00009	1.00374	1.00508
2001[2]	0.99771[3]	1.00009[3]	0.99780[3]	0.99922	1.00365[3]	1.00009[3]	1.00374[3]	1.00508
2002	0.99666[4]	0.99668[4]	0.99335[4]	0.99268	0.98991[4]	0.99668[4]	0.99662[4]	0.99164
2003[5]	0.99915	0.99662	0.99577	0.98848	1.00809	0.99662	1.00468	0.99628
2003[6]	0.99896[7]	0.99662[7]	0.99558[7]	0.98830	1.00809	0.99662	1.00468	0.99628
2004[8]	1.00175[9]	1.00081[9]	1.00256[9]	0.99083	1.00028	1.00081	1.00109	0.99736
2004[10]	1.00164[9]	1.00081[9]	1.00245[9]	0.99072	1.00028	1.00081	1.00109	0.99736
2005[11]	0.99967[12]	1.00094	1.00061[12]	0.99137	0.99115	1.00094	0.99208	0.98946
2005[13]	0.99946[12]	1.00094	1.00040[12]	0.99117	0.99115	1.00094	0.99208	0.98946
2006	1.00185[14]	0.99892	1.00076[14]	0.99198	1.00762	0.99892	1.00653	0.99592
2007	1.00000	0.99858	0.99858	0.99057	1.00234	0.99858	1.00092	0.99683
2008	1.00172	0.99792	0.99963	0.99021	1.00079	0.99792	0.99870	0.99554
2009[15]	1.00206	0.99945	1.00150	0.99170	1.00097	0.99945	1.00041	0.99595
2010[16]	0.99989	0.99945	0.99941	0.99112	1.00141	0.99953	1.00094	0.99688
2011[17]	0.99989	0.99914	0.99903	0.99016	1.00050	0.99914	0.999564	0.99652
2012[18]	1.00050	0.99996	1.00046	0.99061	1.00879	0.99996	1.00874	1.00523

[1] Factors effective for the first half of FY 2001 (October 2000 through March 2001).
[2] Factors effective for the second half of FY 2001 (April 2001 through September 2001).
[3] Incremental factors are applied to FY 2000 cumulative factors.
[4] Incremental factors are applied to the cumulative factors for the first half of FY 2001.
[5] Factors effective for the first half of FY 2003 (October 2002 through March 2003).
[6] Factors effective for the second half of FY 2003 (April 2003 through September 2003).
[7] Incremental factors are applied to FY 2002 cumulative factors.
[8] Factors effective for the first half of FY 2004 (October 2003 through March 2004).
[9] Incremental factors are applied to the cumulative factors for the second half of FY 2003.
[10] Factors effective for the second half of FY 2004 (April 2004 through September 2004).
[11] Factors effective for the first quarter of FY 2005 (September 2004 through December 2004).
[12] Incremental factors are applied to average of the cumulative factors for the first half (October 1, 2003 through March 31, 2004) and second half (April 1, 2004 through September 30, 2004) of FY 2004.
[13] Factors effective for the last three quarters of FY 2005 (January 2005 through September 2005).
[14] Incremental factors are applied to average of the cumulative factors for 2005.
[15] Final factors for FY 2009, including the implementation of section 124 of Pub. L. 110-275, which affects wage indices and GAFs for FY 2009.
[16] Final revised factors for FY 2010 which reflect the effect of the provisions of the Affordable Care Act.
[17] Final factors for FY 2011.
[18] Proposed factors for FY 2012.

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The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor (the national capital rate and the Puerto Rico capital rate are determined separately) for changes in the GAF (including geographic reclassification) and the DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for DSH or IME.

For FY 2011, we established a GAF/DRG budget neutrality factor of 0.9990 (75 FR 50437). For FY 2012, we are proposing to establish a GAF/DRG budget neutrality factor of 1.0005. The GAF/DRG budget neutrality factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs. The incremental change in the proposed adjustment from FY 2011 to FY 2012 is 1.0005. The proposed cumulative change in the capital Federal rate due to this proposed adjustment is 0.9906 (the product of the incremental factors for FYs 1995 through 2011 and the proposed incremental factor of 1.0005 for FY 2012). (We note that averages of the incremental factors that were in effect during FYs 2005 and 2006, respectively, were used in the calculation of the cumulative adjustment of 0.9906 for FY 2012.)

The proposed factor accounts for the proposed MS–DRG reclassifications and recalibration and for proposed changes in the GAFs. It also incorporates the effects on the proposed GAFs of FY 2012 geographic reclassification decisions made by the MGCRB compared to FY 2011 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Exceptions Payment Adjustment Factor

Section 412.308(c)(3) of our regulations requires that the capital standard Federal rate be reduced by an adjustment factor equal to the estimated proportion of additional payments for both regular exceptions and special exceptions under § 412.348 relative to total capital PPS payments. In estimating the proportion of regular exception payments to total capital PPS payments during the transition period, we used the actuarial capital cost model originally developed for determining budget neutrality (described in Appendix B of the FY 2002 IPPS final rule (66 FR 40099)) to determine the exceptions payment adjustment factor, which was applied to both the Federal and hospital-specific capital rates.

Since FY 2002, an adjustment for regular exception payments was no longer necessary in determining the capital Federal rate because, in accordance with § 412.348(b), regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001. Accordingly, in FY 2002 and subsequent fiscal years, no payments are made under the regular exceptions provision (66 FR 39949). Furthermore, there are no longer any remaining hospitals eligible to receive a special exceptions payment under § 412.348(g) because they have reached the limitation on the period for exception payments under § 412.348(g)(7). A hospital qualifying for a special exceptions payment could receive exceptions payments for up to 10 years from the year in which it completed a project that met the applicable criteria under § 412.348(g). However, the project had to be completed no later than the end of the hospital's last cost reporting period beginning before October 1, 2001. Therefore, FY 2012 would be the final year any hospital could have received a special exceptions payment. However, as we indicated above, based on the date the projects were completed, there are no remaining hospitals eligible to receive a special exceptions payment in FY 2012, which negates the need for a special exceptions adjustment for FY 2012. Furthermore, we note that special exceptions adjustments will no longer be made in subsequent years because FY 2012 is the final year payments could have been made to eligible hospitals in accordance with § 412.348(g)(7).

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50439), we estimated that total (special) exceptions payments for FY 2011 would equal 0.04 percent of aggregate payments based on the capital Federal rate. Therefore, we applied an exceptions adjustment factor of 0.9996 (1 − 0.0004) to determine the FY 2011 capital Federal rate. As we stated above, because there are no special exceptions payments in FY 2012, we are proposing to no longer apply an exceptions payment adjustment factor to the proposed capital Federal rate for FY 2012. However, the exceptions reduction factors were not built permanently into the capital rates; that is, the factors were not applied cumulatively in determining the capital Federal rate. Therefore, we are proposing to apply a factor of 1.0004 (1/0.9996) in determining the proposed FY 2012 capital Federal rate to restore the reduction that resulted from the 0.9996 exceptions adjustment factor that was applied in determining the FY 2011 capital Federal rate.

5. Proposed Capital Standard Federal Rate for FY 2012

For FY 2011, we established a capital Federal rate of $420.01 (75 FR 50439). We are proposing to establish an update of 1.5 percent in determining the proposed FY 2012 capital Federal rate for all hospitals. However, as discussed in greater detail in section V.E. of the preamble of this proposed rule, under the statutory authority at section 1886(g) of the Act, consistent with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, we are proposing to make an additional 1.0 percent reduction to the national capital Federal payment rate in FY 2012 to account for the effect of changes in case-mix resulting from documentation and coding changes that do not reflect real changes in the case-mix in light of the adoption of MS–DRGs. Accordingly, we are proposing to apply a cumulative documentation and coding adjustment factor of 0.9479 in determining the proposed FY 2012 capital Federal rate (that is, the existing −0.6 percent adjustment in FY 2008 plus the −0.9 percent adjustment in FY 2009, plus the −2.9 percent adjustment for FY 2011, plus the proposed −1.0 percent adjustment for FY 2012, computed as 1 divided by (1.006 × 1.009 × 1.029 × 1.010). (We note that we did not apply a documentation and coding adjustment to the capital Federal rate in FY 2010 (74 FR 43927).) As a result of the proposed 1.5 percent update and other budget neutrality factors discussed above, we are proposing to establish a national capital Federal rate of $422.54 for FY 2012. The proposed national capital Federal rate for FY 2012 was calculated as follows:

- The proposed FY 2012 update factor is 1.0150, that is, the proposed update is 1.5 percent.
- The proposed FY 2012 budget neutrality adjustment factor that is applied to the capital standard Federal payment rate for proposed changes in the MS–DRG classifications and relative weights and proposed changes in the GAFs is 1.0005.
- The proposed FY 2012 outlier adjustment factor is 0.9406.
- The proposed FY 2012 (special) exceptions payment adjustment factor is 1.0000 because we project that there will be no exceptions payments made in FY 2012 as discussed above in section III.A. of this Addendum. However, we are proposing to apply a factor of 1.0004 (1/0.9996) in determining the proposed FY 2012 capital Federal rate to restore the reduction that resulted from the 0.9996 exceptions adjustment factor applied in determining the FY 2011 capital Federal rate.
- The proposed cumulative adjustment factor for FY 2012 applied to the national capital Federal rate for proposed changes in documentation and coding under the MS–DRGs is 0.9479.

Because the proposed capital Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, indirect medical education costs, and payments to hospitals serving a disproportionate share of low-income patients, we are not proposing to make additional adjustments in the capital standard Federal rate for these factors, other than the proposed budget neutrality factor for proposed changes in the MS–DRG classifications and relative weights and for proposed changes in the GAFs.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2012 affects the computation of the proposed FY 2012 national capital Federal rate in comparison to the FY 2011 national capital Federal rate. The proposed FY 2012 update factor has the effect of increasing the capital Federal rate by 1.5 percent compared to the FY 2011 capital Federal rate. The proposed GAF/DRG budget neutrality factor of 1.0005 has the effect of

increasing the capital Federal rate by 0.05 percent. The proposed FY 2012 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.02 percent compared to the FY 2011 capital Federal rate. The proposed FY 2012 special exceptions payment adjustment factor to restore the FY 2011 exceptions adjustment factor of 0.9996 has the net effect of increasing the proposed FY 2012 national capital Federal rate by 0.04 percent as compared to the FY 2011 national capital Federal rate. The combined effect of all the proposed changes would increase the proposed national capital Federal rate by approximately 0.60 percent compared to the FY 2011 national capital Federal rate.

Comparison of Factors and Adjustments: FY 2011 Capital Federal Rate and Proposed FY 2012 Capital Federal Rate

	FY 2011	Proposed FY 2012	Change	Percent Change
Update Factor[1]	1.0150	1.0150	1.0150	1.50
GAF/DRG Adjustment Factor[1]	0.9990	1.0005	1.0005	0.05
Outlier Adjustment Factor[2]	0.9404	0.9406	1.0002	0.02
Exceptions Adjustment Factor[3]	0.9996	1.0000	1.0004	0.04
MS-DRG Documentation and Coding Adjustment Factor	0.9574[4]	0.9479[5]	0.9901[6]	-0.99
Capital Federal Rate[7]	$420.01	$422.54	1.0060	0.60

[1] The update factor and the GAF/DRG budget neutrality factors are built permanently into the capital rates. Thus, for example, the incremental change from FY 2011 to FY 2012 resulting from the application of the 1.0005 GAF/DRG budget neutrality factor for FY 2012 is a net change of 1.0005.

[2] The outlier reduction factor is not built permanently into the capital rate; that is, the factor is not applied cumulatively in determining the capital rate. Thus, for example, the net change resulting from the application of the FY 2012 outlier adjustment factor is 0.9406/0.9404, or 1.0002.

[3] There are no longer any hospitals eligible to receive special exception adjustments in FY 2012, but since the exceptions payment adjustment is not cumulative, we are restoring the 0.9996 special exceptions adjustment applied to the FY 2011 capital rate.

[4]The documentation and coding adjustment factor includes the -0.6 percent in FY 2008, -0.9 percent in FY 2009, no additional reduction in FY 2010, and the -2.9 percent in FY 2011.

[5]The documentation and coding adjustment factor includes the -0.6 percent in FY 2008, -0.9 percent in FY 2009, no additional reduction in FY 2010, the -2.9 percent in FY 2011, and the proposed -1.0 percent in FY 2012.

[6]The change is measured from the FY 2011 cumulative factor of 0.9574.

[7]Sum of percent change may not sum due to rounding.

6. Proposed Special Capital Rate for Puerto Rico Hospitals

Section 412.374 provides for the use of a blended payment system for payments to hospitals located in Puerto Rico under the PPS for acute care hospital inpatient capital-related costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. Under the broad authority of section 1886(g) of the Act, as discussed in section V. of the preamble of this proposed rule, beginning with discharges occurring on or after October 1, 2004, capital payments to hospitals located in Puerto Rico are based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the capital Federal rate. The Puerto Rico capital rate is derived from the costs of Puerto Rico hospitals only, while the capital Federal rate is derived from the costs of all acute care hospitals participating in the IPPS (including Puerto Rico).

To adjust hospitals' capital payments for geographic variations in capital costs, we apply a GAF to both portions of the blended capital rate. The GAF is calculated using the operating IPPS wage index, and varies depending on the labor market area or rural area in which the hospital is located. We use the Puerto Rico wage index to determine the GAF for the Puerto Rico part of the capital-blended rate and the national wage index to determine the GAF for the national part of the blended capital rate.

Because we implemented a separate GAF for Puerto Rico in FY 1998, we also apply separate budget neutrality adjustments for the national GAF and for the Puerto Rico GAF. However, we apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. The proposed national GAF budget neutrality factor is 1.0088 and the proposed DRG adjustment is 1.0000, for a combined proposed cumulative adjustment of 1.0052 for FY 2012.

In computing the payment for a particular Puerto Rico hospital, the Puerto Rico portion of the capital rate (25 percent) is multiplied by the Puerto Rico-specific GAF for the labor market area in which the hospital is located, and the national portion of the capital rate (75 percent) is multiplied by the national GAF for the labor market area in which the hospital is located (which is computed from national data for all hospitals in the United States and Puerto Rico). In FY 1998, we implemented a 17.78 percent reduction to the Puerto Rico capital rate as a result of Public Law 105–33. In FY 2003, a small part of that reduction was restored.

For FY 2011, the special capital rate for hospitals located in Puerto Rico was $197.66 (75 FR 50441). Consistent with our adjustment to the FY 2011 Puerto Rico-specific standardized amount, under the Secretary's broad authority under section 1886(g) of the Act, we established an adjustment to the Puerto Rico-specific capital rate of –2.6 percent in FY 2011 for the cumulative increase in case-mix due to changes in documentation and coding under the MS–DRGs for FYs 2008 and 2009. The −2.6 percent adjustment to the capital Puerto Rico-specific rate that we made in FY 2011 reflects the entire amount of our current estimate of the effects of documentation and coding that did not reflect real changes in

case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico. Consequently, in this proposed rule, we are not proposing to make any additional adjustments for the effect of documentation and coding that did not reflect real changes in case-mix to the capital Puerto Rico-specific rate for FY 2012. Therefore, with the changes we are proposing to make to the other factors used to determine the capital rate, the proposed FY 2012 special capital rate for hospitals in Puerto Rico is $205.01.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2012

Because the 10-year capital PPS transition period ended in FY 2001, all hospitals (except "new" hospitals under § 412.324(b) and under § 412.304(c)(2)) are paid based on 100 percent of the capital Federal rate in FY 2012.

For purposes of calculating payments for each discharge during FY 2012, the capital standard Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier thresholds for FY 2012 are in section II.A. of this Addendum. For FY 2012, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments is greater than the prospective payment rate for the MS–DRG plus the proposed fixed-loss amount of $23,375.

Currently, as provided in § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021), we rebased and revised the CIPI to a FY 2006 base year to reflect the more current structure of capital costs in hospitals. A complete discussion of this rebasing is provided in section IV. of the preamble of that final rule.

2. Forecast of the CIPI for FY 2012

Based on the latest forecast by IHS Global Insight, Inc. (first quarter of 2011), we are forecasting the FY 2006-based CIPI to increase 1.5 percent in FY 2012. This reflects a projected 1.9 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.1 percent increase in other capital expense prices in FY 2012, partially offset by a projected 0.9 percent decline in vintage-weighted interest expenses in FY 2012. The weighted average of these three factors produces the 1.5 percent increase for the FY 2006-based CIPI as a whole in FY 2012.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages

Historically, hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished on the basis of reasonable costs, subject to a rate-of-increase ceiling. An annual per discharge limit (the target amount as defined in § 413.40(a)) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount for that period was multiplied by the Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to all categories of excluded providers (rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and cancer hospitals).

Payments for services furnished in children's hospitals and cancer hospitals that are excluded from the IPPS continue to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. (We note that, in accordance with § 403.752(a), RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

We are proposing that the FY 2012 rate-of-increase percentage for updating the target amounts for cancer and children's hospitals and RNHCIs be the estimated percentage increase in the FY 2012 IPPS operating market basket, estimated to be 2.8 percent, in accordance with applicable regulations at § 413.40. We also are proposing to use the most recent data available to determine the estimated percentage increase for the FY 2012 IPPS operating market basket. Based on IHS Global Insight, Inc.'s first quarter 2011 forecast, with historical data through the 2010 fourth quarter, the IPPS operating market basket is 2.8 percent for FY 2012. Therefore, for cancer and children's hospitals and RNHCIs, the proposed FY 2012 rate-of-increase percentage that would be applied to the FY 2011 target amounts in order to determine the FY 2012 target amount is 2.8 percent. (We are proposing to use more recent data when determining the estimated percentage increase for the FY 2012 IPPS operating market basket for the final rule, to the extent that these data are available.)

IRFs, IPFs, and LTCHs were previously paid under the reasonable cost methodology. However, the statute was amended to provide for the implementation of prospective payment systems for IRFs, IPFs, and LTCHs. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provide transitioning periods of varying lengths of time during which a portion of the prospective payment is based on cost-based reimbursement rules under 42 CFR part 413 (certain providers do not receive a transitioning period or may elect to bypass the transition as applicable under 42 CFR Part 412, Subparts N, O, and P.) We note that all of the various transitioning periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble and section V. of the Addendum to this proposed rule for the proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2012. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Changes to the Payment Rate for the LTCH PPS for FY 2012

A. Proposed LTCH PPS Standard Federal Rate for FY 2012

1. Background

In section VII. of the preamble of this proposed rule, we discuss our proposed changes to the payment rates, factors, and specific policies under the LTCH PPS for FY 2012.

Under § 412.523(c)(3)(ii) of the regulations, for LTCH PPS rate years beginning RY 2004 through RY 2006, we updated the standard Federal rate annually by a factor to adjust for the most recent estimate of the increases in prices of an appropriate market basket of goods and services for LTCHs. We established this policy of annually updating the standard Federal rate because, at that time, we believed that was the most appropriate method for updating the LTCH PPS standard Federal rate for years after the initial implementation of the LTCH PPS in FY 2003. Thus, under § 412.523(c)(3)(ii), for RYs 2004 through 2006, the annual update to the LTCH PPS standard Federal rate was equal to the previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in covered inpatient LTCH services.

In determining the annual update to the standard Federal rate for RY 2007, based on our ongoing monitoring activity, we believed that, rather than solely using the most recent estimate of the LTCH PPS market basket as the basis of the annual update factor, it was appropriate to adjust the standard Federal rate to account for the effect of documentation and coding in a prior period that was unrelated to patients' severity of illness (71 FR 27818). Accordingly, we established under § 412.523(c)(3)(iii) that the annual update to the standard Federal rate for RY 2007 was zero percent based on the most recent estimate of the LTCH PPS market basket at that time, offset by an adjustment to account for changes in case-mix in prior periods due to the effect of documentation and coding that were unrelated to patients' severity of illness. For RY 2008 through FY 2011, we also considered the effect of documentation and coding that was unrelated to patients' severity of illness in establishing the annual update to the standard Federal rate as set forth in the regulations at § 412.523(c)(3)(iv) through (c)(3)(vii).

Several provisions of the Affordable Care Act revised the annual update to the standard Federal rate, beginning in RY 2010. Specifically, section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment (which we refer to as "the multifactor productivity (MFP) adjustment" as discussed in section VII.E.2.d. of the preamble of this proposed rule) described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.E.2.d. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term "fiscal year" (FY) rather than "rate year" (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we employ "fiscal year" rather than "rate year" for 2011 and subsequent years.)

For FY 2011, consistent with our historical practice, we established an update to the LTCH PPS standard Federal rate based on the full estimated LTCH PPS market basket increase, including the 0.50 percentage point reduction required by sections 1886(m)(3)(A)(i) and (m)(4)(B) of the Act, of 2.0 percent and an adjustment to account for the increase in case-mix in prior periods (FYs 2008 and 2009) that resulted from the effect of documentation and coding practices of −2.5 percent. Accordingly, at § 412.523(c)(vii) of the regulations, we established an annual update of −0.49 percent to the standard Federal rate for FY 2011 (75 FR 50443 through 50444).

In this proposed rule, for FY 2012, as discussed in greater detail in section VII.E.2. of the preamble of this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 1.5 percent based on the full estimated increase in the proposed LTCH PPS market basket of 2.8 percent less the proposed MFP adjustment of 1.2 percentage points required under 1886(m)(3)(A)(ii) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(i) and (m)(4)(C) of the Act. As discussed in greater detail below, for FY 2012, we are not proposing to make an adjustment to account for the increase in case-mix in a prior period (FY 2010) resulting from the effect of documentation and coding.

2. Development of the Proposed FY 2012 LTCH PPS Standard Federal Rate

We continue to believe that the annual update to the LTCH PPS standard Federal rate should be based on the most recent estimate of the increase in the LTCH PPS market basket, including any statutory adjustments. We also continue to believe it is appropriate that the standard Federal rate be offset by an adjustment to account for any effect of documentation and coding practices that does not reflect increased severity of illness. Such an adjustment protects the integrity of the Medicare Trust Funds by ensuring that the LTCH PPS payment rates better reflect the true costs of treating LTCH patients. Consistent with past LTCH payment policy, we have continued to monitor the most recent available LTCH data. Based on an analysis of FY 2010 LTCH claims from the December 2010 update of the MedPAR files, it does not appear that an adjustment for the effect of documentation and coding in FY 2010 is warranted. Therefore, in this proposed rule, we are not proposing to make an adjustment for the effect of documentation and coding during FY 2010 in our proposed annual update to the LTCH PPS standard Federal rate for FY 2012. Furthermore, we are proposing that, consistent with our historical practice of using the best available data, if more recent data subsequently become available, we would examine such data for the final rule to determine if an adjustment for the effect of documentation and coding during FY 2010 is warranted.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444), we established an annual update to the LTCH PPS standard Federal rate for FY 2011 based on the full estimated LTCH PPS market basket increase, including the 0.50 percentage point reduction required by sections 1886(m)(3)(A)(i), (m)(3)(A)(ii), and (m)(4)(B) of the Act, of 2.0 percent and an adjustment to account for the increase in case-mix in prior periods (FYs 2008 and 2009) that resulted from the effect of documentation and coding practices of −2.5 percent. Accordingly, at § 412.523(c)(vii), we established an annual update to the standard Federal rate for FY 2011 of −0.49 percent. That is, we applied an update factor of 0.9951 (calculated as 1.020 × 1 divided by 1.025 = 0.9951 or −0.49 percent) to the RY 2010 Federal rate of $39,794.95 (as established in the June 2, 2010 FY 2010 IPPS/RY 2010 LTCH PPS notice (75 FR 31128 through 31129)) to determine the FY 2011 standard Federal rate. Consequently, we established a standard Federal rate for FY 2011 of $39,599.95, which is applicable to LTCH PPS discharges occurring on or after October 1, 2010, through September 30, 2011.

In this proposed rule, for FY 2012, as noted above and as discussed in greater detail in section VII.E.2. of the preamble of this proposed rule, consistent with our historical practice, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 1.5 percent, based on the full estimated increase in the proposed LTCH PPS market basket of 2.8 percent less the proposed MFP adjustment of 1.2 percentage points required under 1886(m)(3)(A)(ii) and less the 0.1 percentage point required by sections 1886(m)(3)(A)(i) and(m)(4)(C) of the Act. Accordingly, the proposed update factor to the standard Federal rate for FY 2012 is 1.5 percent. That is, under proposed § 412.523(c)(viii), we are proposing to apply a factor of 1.015 to the FY 2011 standard Federal rate of $39,599.95 (as established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50444)) to determine the FY 2012 standard Federal rate. Furthermore, as discussed in greater detail in section VII.E.3. of the preamble of this proposed rule, for FY 2012, we are proposing to apply an area wage level budget neutrality factor of 0.99723 to the standard Federal rate to ensure that any changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Consequently, we are proposing to establish a standard Federal rate for FY 2012 of $40,082.61 (calculated as $39,599.95 × 1.015 × 0.99723), which would be applicable to LTCH PPS discharges occurring on or after October 1, 2011, through September 30, 2012.

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2012

1. Background

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal rate to account for differences in LTCH area wage levels at § 412.525(c). The labor-related share of the LTCH PPS standard Federal rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56015), when we implemented the LTCH PPS, we established a 5-year transition to the full area wage index level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH wage index values are the full LTCH PPS wage index values calculated

based on acute care hospital inpatient wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. For additional information on the phase-in of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56017 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. Geographic Classifications/Labor Market Area Definitions

As discussed in the August 30, 2002 LTCH PPS final rule, which implemented the LTCH PPS (67 FR 56015 through 56019), in establishing an adjustment for area wage levels, the labor-related portion of a LTCH's Federal prospective payment is adjusted by using an appropriate wage index based on the labor market area in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment at existing § 412.525(c) is made on the basis of the location of the LTCH in either an urban area or a rural area as defined in § 412.503. Currently under the LTCH PPS at § 412.503, an "urban area" is defined as a Metropolitan Statistical Area (which would include a metropolitan division, where applicable) as defined by the Executive OMB and a "rural area" is defined as any area outside of an urban area.

In the RY 2006 LTCH PPS final rule (70 FR 24184 through 24185), in regulations at § 412.525(c), we revised the labor market area definitions used under the LTCH PPS effective for discharges occurring on or after July 1, 2005, based on the Executive OMB's CBSA designations, which are based on 2000 Census data. We made this revision because we believe that the CBSA-based labor market area definitions will ensure that the LTCH PPS wage index adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We note that these are the same CBSA-based designations implemented for acute care hospitals under the IPPS at § 412.64(b), effective October 1, 2004 (69 FR 49026 through 49034). (For further discussion of the CBSA-based labor market area (geographic classification) definitions currently used under the LTCH PPS, we refer readers to the RY 2006 LTCH PPS final rule (70 FR 24182 through 24191).) We have updated the LTCH PPS CBSA-based labor market area definitions annually since they were adopted for RY 2006 (73 FR 26812 through 26814, 74 FR 44023 through 44204, and 75 FR 50444 through 50445).

In OMB Bulletin No. 10–2, issued on December 1, 2009, OMB announced that the CBSA changes in that bulletin would be the final update prior to the 2010 Census of Population and Housing. We adopted those changes under the LTCH PPS in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50444 through 50445), effective beginning October 1, 2010, and they are also reflected in this FY 2012 proposed rule. In 2013, OMB plans to announce new area delineations based on its 2010 standards (75 FR 37246) and the 2010 Census data.

The OMB bulletin is available on the OMB Web site at *http://www.whitehouse.gov/OMB—go* to "Agency Information" and click on "Bulletins".

3. Proposed LTCH PPS Labor-Related Share

Under the adjustment for differences in area wage levels at § 412.525(c), the labor-related share of a LTCH's PPS Federal prospective payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs (wages and salaries, employee benefits, professional fees, and all other labor-intensive services) and a labor-related portion of capital costs using the applicable LTCH PPS market basket. Currently, as established in the RY 2007 LTCH PPS final rule (71 FR 27829 through 27830), the LTCH PPS labor-related share is based on the relative importance of the labor-related share of operating costs and capital costs of the rehabilitation, psychiatric, and long-term care hospital (RPL) market basket based on FY 2002 data, as those were the best available data at that time that reflected the cost structure of LTCHs. For the past 4 years (RY 2008, RY 2009, RY 2010, and FY 2011), we updated the LTCH PPS labor-related share annually based on the latest available data for the FY 2002-based RPL market basket. For FY 2011, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 20445), we established a labor-related share of 75.271 percent based on the best available data at that time for the FY 2002-based RPL market basket for FY 2011. (Additional background information on the historical development of the labor-related share under the LTCH PPS and the development of the RPL market basket can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830).)

In section VII.D. of the preamble of this proposed rule, we are proposing to revise and rebase the market basket used under the LTCH PPS beginning in FY 2012. Specifically, we are proposing to adopt the newly created FY 2008-based RPL market basket. We are not proposing to change our definition of the labor-related share. However, we are proposing to rename our aggregate cost categories from "labor-intensive" and "nonlabor-intensive" services to "labor-related" and "nonlabor-related" services (as discussed. in section VII.D.3.b. of the preamble of this proposed rule). As discussed in section VII.D.3.f. of the preamble of this proposed rule, we are proposing a labor-related share under the LTCH PPS for FY 2012 based on IHS Global Insight, Inc.'s first quarter 2011 forecast of the proposed FY 2008-based RPL market basket for FY 2012, as these are the most recent available data at this time that reflect the cost structure of LTCHs. We are also proposing that the labor-related share for FY 2012 is the sum of the proposed FY 2012 relative importance of each labor-related cost category of the proposed FY 2008-based RPL market basket, and reflects the different rates of price change for these cost categories between the proposed base year (FY 2008) and FY 2012.

As discussed in greater detail in section VII.D.3.f. of the preamble of this proposed rule, the sum of the proposed relative importance for FY 2012 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All-Other: Labor-related Services) is 66.689 percent and the proposed labor-related share of capital costs is 3.645 percent. Thus, under the authority set forth in section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to establish a labor-related share of 70.334 percent (66.689 percent + 3.645 percent) under the LTCH PPS for the FY 2012, which would be effective for discharges occurring on or after October 1, 2011, and through September 30, 2012. Consistent with our historical practice of using the best data available, we also are proposing that if more recent data are available to determine the labor-related share used under the LTCH PPS for FY 2012, we would use these data for determining the FY 2012 LTCH PPS labor-related share in the final rule.

4. Proposed LTCH PPS Wage Index for FY 2012

Historically, under the LTCH PPS, we have established LTCH PPS wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on a LTCH's actual location without regard to the urban or rural designation of any related or affiliated provider.

In the FY 2011 LTCH PPS final rule (75 FR 50445 through 50446), we calculated the FY 2011 LTCH PPS wage index values using the same data used for the FY 2011 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2007), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2011 LTCH PPS wage index values consistent with the urban and rural geographic classifications (labor market areas) and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). We also continued to use our existing policy for determining wage index values in areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable wage index values under the LTCH PPS for FY 2012, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate adjustments under the LTCH PPS, we are proposing to use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2008, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act. We are proposing to use FY 2008 data because these data are the most recent

complete data available. These are the same data used to compute the proposed FY 2012 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule. (For our rationale for using IPPS hospital wage data as a proxy for determining the wage index values used under the LTCH PPS, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44024 through 44025).)

The proposed FY 2012 LTCH PPS wage index values we are presenting in this proposed rule are computed consistent with the urban and rural geographic classifications (labor market areas) discussed above in section V.B.2. of the Addendum to this proposed rule and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus or campuses are located (as discussed in section III.F. of the preamble of this proposed rule). Furthermore, we are proposing that, in determining the FY 2012 LTCH PPS wage index values in this proposed rule, we continue to use our existing policy for determining wage index values in areas where there are no IPPS wage data.

As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50446), we established a methodology for determining LTCH PPS wage index values for areas that have no IPPS wage data in the RY 2009 LTCH PPS final rule, and we are proposing to continue to use this methodology for FY 2012. (We refer readers to 73 FR 26817 through 26818 for an explanation of and rationale for our policy.) Under this methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State. As was the case in FY 2011, there are currently no LTCHs located in labor areas without IPPS hospital wage data (or IPPS hospitals) for FY 2012. However, we calculate proposed LTCH PPS wage index values for these areas using our established methodology in the event that, in the future, a LTCH should open in one of those areas.

Based on the FY 2008 IPPS wage data that we are proposing to use to determine the proposed FY 2012 LTCH PPS wage index values in this proposed rule, there are no IPPS wage data for the urban area Hinesville-Fort Stewart, GA (CBSA 25980). Consistent with the methodology discussed above, we are proposing to calculate the FY 2012 wage index value for CBSA 25980 as the average of the proposed wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

For FY 2012, using our established methodology, we are proposing to calculate a LTCH PPS wage index value for rural areas with no IPPS wage data using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State (for an explanation of this policy, we refer readers to 73 FR 26818). For this purpose, we define "contiguous" as sharing a border. Based on the FY 2008 IPPS wage data that we are proposing to use to determine the proposed FY 2012 LTCH PPS wage index values in this proposed rule, there are no IPPS wage data for the rural area of Massachusetts (CBSA code 22). Consistent with the methodology described above, the proposed FY 2012 wage index value for rural Massachusetts is computed using the unweighted average of the wage indices from all of the CBSAs contiguous to the rural counties in that State. Specifically, the entire Massachusetts rural area consists of Dukes and Nantucket counties. The borders of Dukes and Nantucket counties are "contiguous" with Barnstable County, MA, and Bristol County, MA. Therefore, the proposed FY 2012 LTCH PPS wage index value for rural Massachusetts is computed as the unweighted average of the proposed FY 2012 wage indexes for Barnstable County and Bristol County, which are shown in Table 12A in the Addendum to this proposed rule). As noted above, as IPPS wage data are dynamic, it is possible that rural areas without IPPS wage data will vary in the future.

The proposed FY 2012 LTCH wage index values that would be applicable for LTCH discharges occurring on or after October 1, 2011, through September 30, 2012, are presented in Table 12A (for urban areas) and Table 12B (for rural areas) in the Addendum of this proposed rule.

5. Proposed Budget Neutrality Adjustment for Changes to the Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. However, there are currently no statutory or regulatory requirements that the annual update to the LTCH PPS area wage level adjustment at existing § 412.525(c) (that is, the wage index and the labor-related share) be budget neutral such that estimated aggregate LTCH PPS payments would be unaffected (that is, would be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes). In section VII.E.3. of the preamble of this proposed rule, under § 412.525(c), we are proposing that, beginning in FY 2012, any changes to the wage index values or labor-related share be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected, that is, would be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this proposal, we are also proposing to determine an area wage level adjustment budget neutrality factor that would be applied to the standard Federal rate to ensure that any changes to the area wage level adjustment would be budget neutral such that any changes to the wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Therefore, under proposed § 412.523(d)(4), we are proposing to apply an area wage level adjustment budget neutrality factor of 0.99723 (determined under the proposed methodology described in section VII.E.3. of the preamble of this proposed rule) to determine the proposed FY 2012 LTCH PPS standard Federal rate. (The development of the proposed LTCH PPS standard Federal rate for FY 2012 is discussed in section V.A.2. of this Addendum.)

C. Proposed LTCH PPS Cost-of-Living Adjustment for LTCHs Located in Alaska and Hawaii

In the August 30, 2002 final rule (67 FR 56022), we established, under § 412.525(b), a cost-of-living adjustment (COLA) for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels described above.

For FY 2011 and in prior years, we used the most recent updated COLA factors obtained from the U.S. Office of Personnel Management (OPM) Web site at *http://www.opm.gov/oca/cola/rates.asp* to adjust the payments for LTCHs in Alaska and Hawaii. Sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009) transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Public Law 111–84, locality pay is being phased in over a 3-year period beginning in January 2010 with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality.

We do not believe it is appropriate to propose to use either the 2010 or 2011 reduced factors for adjusting the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska or Hawaii.

Therefore, for FY 2012, we are proposing to continue to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which are based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii. We believe using these COLA factors would appropriately adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii consistent with § 412.525(b). (We note that this proposal is consistent with the proposed adjustment for cost-of-living in Alaska and Hawaii for IPPS hospitals discussed in section II.B.2. of this Addendum.) We invite public comment on this proposal.

In this proposed rule, for FY 2012, under the broad authority conferred upon the

Secretary by section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate adjustments under the LTCH PPS, consistent with our current policy, we are proposing to apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the proposed factors listed in the chart below because they are the most recent available data at this time. As discussed above, these factors were obtained from the OPM and are also proposed to be used under the IPPS for FY 2012.

Proposed Cost-of-Living Adjustment Factors for Alaska and Hawaii Hospitals for the LTCH PPS for FY 2012

Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
All other areas of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.18
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

(The above factors are based on data obtained from the U.S. Office of Personnel Management Web site at: http://www.opm.gov/oca/cola/rates.asp.)

D. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. Background

Under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA, in the regulations at § 412.525(a), we established an adjustment for additional payments for outlier cases that have extraordinarily high costs relative to the costs of most discharges. We refer to these cases as high cost outliers (HCOs). Providing additional payments for outliers strongly improves the accuracy of the LTCH PPS in determining resource costs at the patient and hospital level. These additional payments reduce the financial losses that would otherwise be incurred when treating patients who require more costly care and, therefore, reduce the incentives to underserve these patients. We set the outlier threshold before the beginning of the applicable rate year so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS.

Under § 412.525(a) in the regulations (in conjunction with § 412.503), we make outlier payments for any discharges if the estimated cost of a case exceeds the adjusted LTCH PPS payment for the MS–LTC–DRG plus a fixed-loss amount. Specifically, in accordance with § 412.525(a)(3) (in conjunction with § 412.503), we make an additional payment to an HCO case that is equal to 80 percent of the difference between the estimated cost of the patient case and the outlier threshold, which is the sum of the adjusted Federal prospective payment for the MS–LTC–DRG and the fixed-loss amount. The fixed-loss amount is the amount used to limit the loss that a hospital will incur under the outlier policy for a case with unusually high costs. This results in Medicare and the LTCH sharing financial risk in the treatment of extraordinarily costly cases. Under the LTCH PPS HCO policy, the LTCH's loss is limited to the fixed-loss amount and a fixed percentage of costs above the outlier threshold (adjusted MS–LTC–DRG payment plus the fixed-loss amount). The fixed percentage of costs is called the marginal cost factor. We calculate the estimated cost of a case by multiplying the Medicare allowable covered charge by the hospital's overall hospital cost-to-charge ratio (CCR).

Under the LTCH PPS HCO policy at § 412.525(a), we determine a fixed-loss amount, that is, the maximum loss that a LTCH can incur under the LTCH PPS for a case with unusually high costs before the LTCH will receive any additional payments. We calculate the fixed-loss amount by estimating aggregate payments with and without an outlier policy. The fixed-loss amount results in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments. Currently, MedPAR claims data and CCRs based on data from the most recent Provider-Specific File (PSF) (or from the applicable statewide average CCR if a LTCH's CCR data are faulty or unavailable) are used to establish a fixed-loss threshold amount under the LTCH PPS.

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

The following is a discussion of CCRs that are used in determining payments for HCO and SSO cases under the LTCH PPS, at § 412.525(a) and § 412.529, respectively. Although this section is specific to HCO cases, because CCRs and the policies and methodologies pertaining to them are used in determining payments for both HCO and SSO cases (to determine the estimated cost of the case at § 412.529(d)(2)), we are discussing the determination of CCRs under the LTCH PPS for both of these types of cases simultaneously.

In determining both HCO payments (at § 412.525(a)) and SSO payments (at § 412.529), we calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. In general, we use the LTCH's overall CCR, which is computed based on either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period, in accordance with § 412.525(a)(4)(iv)(B) and § 412.529(f)(4)(ii) for HCOs and SSOs, respectively. (We note that, in some instances, we use an alternative CCR, such as the statewide average CCR in accordance with the regulations at § 412.525(a)(4)(iv)(C) and § 412.529(f)(4)(iii), or a CCR that is specified by CMS or that is requested by the hospital under the provisions of the regulations at § 412.525(a)(4)(iv)(A) and § 412.529(f)(4)(i).) Under the LTCH PPS, a single prospective payment per discharge is made for both inpatient operating and capital-related costs. Therefore, we compute a single "overall" or "total" LTCH-specific CCR based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total charges. Specifically, a LTCH's CCR is calculated by dividing a LTCH's total Medicare costs (that is, the sum of its operating and capital inpatient routine and ancillary costs) by its total Medicare charges (that is, the sum of its

operating and capital inpatient routine and ancillary charges).

b. LTCH Total CCR Ceiling

Generally, a LTCH is assigned the applicable statewide average CCR if, among other things, a LTCH's CCR is found to be in excess of the applicable maximum CCR threshold (that is, the LTCH CCR ceiling). This is because CCRs above this threshold are most likely due to faulty data reporting or entry, and, therefore, CCRs based on erroneous data should not be used to identify and make payments for outlier cases. Thus, under our established policy, generally, if a LTCH's calculated CCR is above the applicable ceiling, the applicable LTCH PPS statewide average CCR is assigned to the LTCH instead of the CCR computed from its most recent (settled or tentatively settled) cost report data.

In accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCOs and § 412.529(f)(4)(iii)(B) for SSOs, using our established methodology for determining the LTCH total CCR ceiling (described above), based on IPPS total CCR data from the December 2010 update of the PSF, we are proposing to establish a total CCR ceiling of 1.210 under the LTCH PPS that would be effective for discharges occurring on or after October 1, 2011, through September 30, 2012. Consistent with our historical policy of using the best available data, we also are proposing that if more recent data become available, we would use such data to establish a total CCR ceiling for FY 2012 in the final rule.

c. Proposed LTCH Statewide Average CCRs

Our general methodology established for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling (described above) because it is based on "total" IPPS CCR data. Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C) and the SSO policy at § 412.529(f)(4)(iii), the fiscal intermediary or MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for a LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (for this purpose, consistent with current policy, a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose CCR is in excess of the LTCH CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the fiscal intermediary or MAC may consider in determining a LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as a LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data and using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS total CCR data from the December 2010 update of the PSF, we are proposing to establish LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2011, through September 30, 2012, in Table 8C of the Addendum to this proposed rule. Consistent with our historical policy of using the best available data, we also are proposing that if more recent data become available, we would use such data to establish LTCH PPS statewide average total CCRs for FY 2012 in the final rule.

All areas in the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C listed in section VI. of the Addendum to this proposed rule and available via the Internet. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although North Dakota and Puerto have areas that are designated as rural, there are no short-term, acute care IPPS hospitals or LTCHs located in those areas as of March 2011. Therefore, there is no rural statewide average total CCR listed for rural North Dakota in Table 8C listed in section VI. of the Addendum to this proposed rule and available via the Internet.

In addition, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, in this proposed rule, we are using, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We use this proxy because we believe that the CCR data on the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of LTCH HCO and SSO Payments

We note that under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(D) and the LTCH PPS SSO policy at § 412.529(f)(4)(iv), the payments for HCO and SSO cases, respectively, are subject to reconciliation. Specifically, any reconciliation of outlier payments is based on the CCR that is calculated based on a ratio of cost-to-charge data computed from the relevant cost report determined at the time the cost report coinciding with the discharge is settled. For additional information, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4) as added by Change Request 7192 (Transmittal 2111; December 3, 2010) and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. Establishment of the Proposed LTCH PPS Fixed-Loss Amount for FY 2012

When we implemented the LTCH PPS, as discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56026), under the broad authority of section 123 of the BBRA as amended by section 307(b) of BIPA, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS. To determine the fixed-loss amount, we estimate outlier payments and total LTCH PPS payments for each case using claims data from the MedPAR files. Specifically, to determine the outlier payment for each case, we estimate the cost of the case by multiplying the Medicare covered charges from the claim by the LTCH's CCR. Under § 412.525(a)(3) (in conjunction with § 412.503), if the estimated cost of the case exceeds the outlier threshold, we make an outlier payment equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (that is, the sum of the adjusted Federal prospective payment for the MS–LTC–DRG and the fixed-loss amount).

In this proposed rule, we are proposing to continue to use our existing methodology to calculate the proposed fixed-loss amount for FY 2012 (based on updated data and the proposed rates and policies presented in this proposed rule) in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments. (For an explanation of our rationale for establishing an HCO payment "target" of 8 percent of total estimated LTCH payments, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024).) Consistent with our historical practice of using the best data available, in determining the proposed fixed-loss amount for FY 2012, we are using the most recent available LTCH claims data and CCR data at this time. Specifically, we are using LTCH claims data from the December 2010 update of the FY 2010 MedPAR files and CCRs from the December 2010 update of the PSF to determine a fixed-loss amount that would result in estimated outlier payments projected to be equal to 8 percent of total estimated payments in FY 2012 because these data are the most recent complete LTCH data currently available. Consistent with the historical practice of using the best available data, we also are proposing that if more recent LTCH claims data become available, we would use them for determining the fixed-loss amount for FY 2012 in the final rule. Furthermore, we are proposing to determine the proposed FY 2012 fixed-loss amount based on the proposed MS–LTC–DRG classifications and relative weights from the version of the GROUPER that would be in effect as of the beginning of FY 2012, that is, proposed Version 29.0 of the GROUPER.

Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of BIPA, we are proposing to establish a fixed-loss amount of $19,270 for FY 2012. Thus, we would make an additional payment to an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted Federal LTCH payment for the MS–LTC–DRG and the proposed fixed-loss amount of $19.270). We also note that the proposed fixed-loss amount of $19,270 for FY 2012 is slightly higher than the FY 2011 fixed-loss amount of $18,785. Based on

our payment simulations using the most recent available data at this time, the proposed increase in the fixed-loss amount for FY 2012 would be necessary to maintain the existing requirement that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments. (For further information on the existing 8 percent HCO "target" requirement, as noted above, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024.) Maintaining the fixed-loss amount at the current level would result in HCO payments that are greater than the current regulatory 8-percent requirement because a higher fixed-loss amount would result in fewer cases qualifying as outlier cases as well as a decrease in the amount of the additional payment for an HCO case because the maximum loss that a LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be larger. For these reasons, we believed that proposing a slight increase in the fixed-loss amount is appropriate and necessary to maintain that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments as required under § 412.525(a).

4. Application of Outlier Policy to SSO Cases

As we discussed in the August 30, 2002 final rule (67 FR 56026), under some rare circumstances, a LTCH discharge could qualify as a SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as a HCO case. In this scenario, a patient could be hospitalized for less than five-sixths of the geometric average length of stay for the specific MS–LTC–DRG, and yet incur extraordinarily high treatment costs. If the estimated costs exceeded the HCO threshold (that is, the SSO payment plus the fixed-loss amount), the discharge is eligible for payment as a HCO. Thus, for a SSO case in FY 2012, the HCO payment would be 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed fixed-loss amount of $19,270 and the amount paid under the SSO policy as specified in § 412.529).

E. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2012

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal rate. Under § 412.525(c), the standard Federal rate is adjusted to account for differences in area wages by multiplying the labor-related share of the standard Federal rate by the appropriate LTCH PPS wage index (as shown in Tables 12A and 12B listed in section VI. of the Addendum of this proposed rule and available via the Internet). The standard Federal rate is also adjusted to account for the higher costs of hospitals in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal rate by the appropriate cost-of-living factor (shown in the chart in section V.C.5. of the Addendum of this proposed rule) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish a proposed standard Federal rate for FY 2012 of $40,082.61, as discussed above in section V.A.2. of the Addendum of this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS Federal rate for FY 2012 in the following example:

Example:

During FY 2012, a Medicare patient is in a LTCH located in Chicago, Illinois (CBSA 16974). The FY 2012 LTCH PPS wage index value for CBSA 16974 is 1.0632 (Table 12A listed in section VI. of the Addendum of this proposed rule and available via the Internet). The Medicare patient is classified into proposed MS–LTC–DRG 28 (Spinal Procedures with MCC), which has a proposed relative weight for FY 2012 of 1.7360 (Table 11 listed in section VI. of the Addendum of this proposed rule and available via the Internet).

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient, we compute the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed standard Federal rate ($40,082.61) by the proposed labor-related share (70.334 percent) and the proposed wage index value (1.0632). This wage-adjusted amount is then added to the nonlabor-related portion of the unadjusted proposed standard Federal rate (29.666 percent; adjusted for cost of living, if applicable) to determine the adjusted Federal rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (1.7360) to calculate the total adjusted proposed Federal LTCH PPS prospective payment for FY 2012 ($72,676.47). The table below illustrates the components of the calculations in this example.

Proposed Unadjusted Standard Federal Prospective Payment Rate	$40,082.61
Proposed Labor-Related Share	x 0.70334
Proposed Labor-Related Portion of the Federal Rate	= $28,191.70
Proposed Wage Index (CBSA 16974)	x 1.0632
Proposed Wage-Adjusted Labor Share of Federal Rate	= $29,973.42
Proposed Nonlabor-Related Portion of the Federal Rate ($40,082.61 x 0.29666)	+ $11,890.91
Proposed Adjusted Federal Rate Amount	= $41,864.33
Proposed MS-LTC-DRG 28 Relative Weight	x 1.7360
Total Proposed Adjusted Federal Prospective Payment	= $72,676.47

VI. Tables Referenced in this Proposed Rule and Available Only Through the Internet on the CMS Web Site

This section lists the tables referred to throughout the preamble of this proposed rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, IPPS tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 5, 6A, 6B, 6C, 6D, 6E, 6F, 7A, 7B, 8A, 8B, 9A, 9C, and 10, and LTCH PPS tables 8C, 11, 12A, and 12B will no longer be published as part of the annual IPPS/LTCH PPS proposed and final rulemakings. Instead, these tables, along with new LTCH PPS tables 13A and 13B, and new IPPS table 14 will be available only through the Internet. IPPS tables 1A, 1B, 1C, and 1D, and LTCH PPS table 1E, displayed at the end of this section, will continue to be published in the **Federal Register** as part of the annual and final rules. We note that previously tables 6G, 6H, 6I, 6I.1, 6I.2, 6J, 6J.1, 6J.2, and 6K were already made available only through the Internet. We will continue to post these tables through the Internet.

Readers who experience any problems accessing any of the tables that are posted on

the CMS Web sites identified below should contact Ing Jye Cheng at (410) 786–4548.

The following IPPS tables for this FY 2012 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp.* Click on the link on the left side of the screen titled, "FY 2012 IPPS Proposed Rule Home Page" or "Acute Inpatient—Files for Download".

Table 2.—Acute Care Hospitals Case-Mix Indexes for Discharges Occurring in Federal Fiscal Year 2010; Proposed Hospital Wage Indexes for Federal Fiscal Year 2012; Hospital Average Hourly Wages for Federal Fiscal Years 2010 (2006 Wage Data), 2011 (2007 Wage Data), and 2012 (2008 Wage Data); and 3-Year Average of Hospital Average Hourly Wages

Table 3A.—Proposed FY 2012 and 3-Year Average Hourly Wage for Acute Care Hospitals in Urban Areas by CBSA

Table 3B.—Proposed FY 2012 and 3-Year Average Hourly Wage for Acute Care Hospitals in Rural Areas by CBSA

Table 4A.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Urban Areas by CBSA and by State—FY 2012

Table 4B.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Rural Areas by CBSA and by State—FY 2012

Table 4C.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals That Are Reclassified by CBSA and by State—FY 2012

Table 4D.—States Designated as Frontier, with Acute Care Hospitals Receiving at a Minimum the Frontier State Floor Wage Index [1]; Urban Areas with Acute Care Hospitals Receiving the Proposed Statewide Rural Floor Wage Index—FY 2012

Table 4E.—Urban CBSAs and Constituent Counties for Acute Care Hospitals—FY 2012

Table 4F.—Proposed Puerto Rico Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals by CBSA—FY 2012

Table 4J.—Proposed Out-Migration Adjustment for Acute Care Hospitals—FY 2012

Table 5.—List of Proposed Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2012

Table 6A.—Proposed New Diagnosis Codes—FY 2012

Table 6B.—Proposed New Procedure Codes—FY 2012

Table 6C.—Proposed Invalid Diagnosis Codes—FY 2012

Table 6D.— Proposed Invalid Procedure Codes—FY 2012

Table 6E.—Proposed Revised Diagnosis Code Titles—FY 2012

Table 6F.—Proposed Revised Procedure Code Titles—FY 2012

Table 6G.—Proposed Additions to the CC Exclusions List—FY 2012

Table 6H.—Proposed Deletions from the CC Exclusions List—FY 2012

Table 6I.—Proposed Complete MCC List—FY 2012

Table 6I.1.—Proposed Additions to the MCC List—FY 2012

Table 6I.2.—Proposed Deletions to the MCC List—FY 2012

Table 6J.—Proposed Complete CC List—FY 2012

Table 6J.1.—Proposed Additions to the CC List—FY 2012

Table 6J.2.—Proposed Deletions to the CC List—FY 2012

Table 6K.—Proposed Complete List of CC Exclusions—FY 2012

Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2010 MedPAR Update—December 2010 GROUPER V28.0 MS–DRGs

Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2010 MedPAR Update—December 2010 GROUPER V29.0 MS–DRGs

Table 8A.—Proposed FY 2012 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Proposed FY 2012 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 9A.—Hospital Reclassifications and Redesignations—FY 2012

Table 9C.—Hospitals Redesignated as Rural under Section 1886(d)(8)(E) of the Act—FY 2012

Table 10.—Proposed Geometric Mean Plus the Lesser of .75 of the National Adjusted Operating Standardized Payment Amount (Increased to Reflect the Difference Between Costs and Charges) or .75 of One Standard Deviation of Mean Charges by Medicare Severity Diagnosis-Related Groups (MS–DRGs)

Table 14.—List of Hospitals with Fewer than 1,600 Medicare Discharges Based on the December 2010 Update of the FY 2010 MedPAR File and Their Proposed FY 2012 Low-Volume Payment Adjustment

The following LTCH PPS tables for this FY 2012 proposed rule are available only through the Internet on the CMS Web site at *http://www.cms.gov/LongTermCareHospitalPPS/LTCHPPSRN/list.asp* under the list item for Regulation Number CMS–1518–P.

Table 8C.—Proposed FY 2012 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for Discharges Occurring from October 1, 2011 through September 30, 2012 under the LTCH PPS

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2011 through September 30, 2012

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring From October 1, 2011 through September 20, 2012

Table 13A.—Composition of Proposed Low-Volume Quintiles for MS–LTC–DRGs—FY 2012

Table 13B.—Proposed No-Volume MS–LTC–DRG Crosswalk for FY 2012

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TABLE 1A.—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (68.8 PERCENT LABOR SHARE/31.2 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2012

Full Update (1.50 Percent)		Reduced Update (-0.50 Percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
$3,531.06	$1,601.30	$3,461.48	$1,569.75

TABLE 1B.—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)--FY 2012

Full Update (1.50 Percent)		Reduced Update (-0.50 Percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
$3,182.06	$1,950.30	$3,119.36	$1,911.87

TABLE 1C.—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR--FY 2012

	Rates if Wage Index is Greater Than 1		Rates if Wage Index is Less Than or Equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National	$3,531.06	$1,601.30	$3,182.06	$1,950.30
Puerto Rico	$1,551.84	$947.10	$1,549.34	$949.60

TABLE 1D.—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2012

	Rate
National	$422.54
Puerto Rico	$205.01

TABLE 1E.— PROPOSED LTCH STANDARD FEDERAL PROSPECTIVE PAYMENT RATE--FY 2012

	Rate
Standard Federal Rate	$40,082.61

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Appendix A: Regulatory Impact Analysis

I. Introduction

A. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011) the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We have determined that this proposed rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the proposed changes for FY 2012 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million among different types of inpatient cases. The proposed applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated $498 million decrease in FY 2012 operating payments (or −0.5 percent change) and an estimated $146 million increase in FY 2012 capital payments (or 1.8 percent change). The impact analysis of the capital payments can be found in section VIII. of this Appendix. In addition, as described in section IX. of this Appendix, LTCHs are expected to experience a change in payments by $95 million (or 1.9 percent).

Our operating impact estimate includes the proposed −2.5 percent documentation and coding adjustment applied to the hospital-specific rates and the proposed –3.15 percent adjustment for documentation and coding changes to the IPPS standardized amounts. In addition, our operating impact estimate includes the proposed 1.5 percent hospital update to the standardized amount (which includes the proposed 2.8 percent market basket update with the reduction of 1.2 percentage point for the multifactor productivity adjustment and the 0.1 percentage point reduction required under the Affordable Care Act). Finally, our operating impact estimate includes the proposed 1.1 percent update to the standardized amount and the 0.9 percent update to the hospital-specific rates in light of DC Circuit's decision in *Cape Cod* v. *Sebelius* (630 F.3d 203 (D.C. Cir. 2011)). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which would also affect overall payment changes.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $34.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 33 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: *http://www.sba.gov/contractingopportunities/sizestandardtopics/tableofsize/index.html.*)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this proposed rule relating to acute care hospitals would have a significant impact on small entities as explained in this Appendix. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section IX. of this Appendix. Medicare fiscal intermediaries and MACs are not considered to be small entities. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our proposed regulatory flexibility analysis. Therefore, we are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we now define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I and section VI. of this Appendix for the quantitative effects of the proposed policy changes under the IPPS for operating costs.)

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold level is approximately $136 million. This proposed rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

The analysis that begins in section II of this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. The proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant.

B. Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS payment system.

II. Objectives of the IPPS

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate

costs. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe the changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

III. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2012, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but, generally, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix.

IV. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 32 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, only the 46 such hospitals in Maryland remain excluded from the IPPS pursuant to the waiver under section 1814(b)(3) of the Act.

As of March 2011, there are 3,419 IPPS acute care hospitals to be included in our analysis. This represents about 64 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,342 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. (We refer readers to section VII.M. of this Appendix for a further description of the impact of CAH-related proposed policy changes.) There are also 1,290 IPPS-excluded hospitals and 2,119 IPPS-excluded hospital units. These IPPS-excluded hospitals and units include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, and cancer hospitals, which are paid under separate payment systems. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and policy changes to the LTCH PPS for FY 2012 are discussed in section IX. of this Appendix.

V. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2011, there were 3,409 hospitals and hospital units excluded from the IPPS. Of these, 78 children's hospitals, 11 cancer hospitals, and 17 RNHCIs are being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. The remaining providers, 235 rehabilitation hospitals and 940 rehabilitation units, and 437 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 512 psychiatric hospitals and 1,179 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated above, IRFs and IPFs are not affected by proposed rate updates discussed in this proposed rule. The impacts of the changes to LTCHs are discussed in section IX. of this Appendix.

In the past, certain hospitals and units excluded from the IPPS have been paid based on their reasonable costs subject to limits as established by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Cancer and children's hospitals continue to be paid on a reasonable cost basis subject to TEFRA limits for FY 2012. For these hospitals (cancer and children's hospitals), consistent with the authority provided in section 1886(b)(3)(B)(ii) of the Act, the update is the FY 2012 percentage increase in the IPPS operating market basket. In compliance with section 404 of the MMA, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43930), we replaced the FY 2002-based IPPS operating and capital market baskets with the revised and rebased FY 2006-based IPPS operating and capital market baskets. Therefore, consistent with current law, based on IHS Global Insight, Inc.'s 2011 first quarter forecast, with historical data through the 2010 fourth quarter, we are estimating that the FY 2012 update based on the IPPS operating market basket will be 2.8 percent (that is, the current estimate of the market basket rate-of-increase). However, the Affordable Care Act requires an adjustment for multifactor productivity (currently estimated to be −1.2 percentage points) and a 0.1 percentage point reduction to the market basket update resulting in a proposed 1.5 percent applicable percentage increase for IPPS hospitals. RNCHIs, children's hospitals and cancer hospitals are not subject to the reduction in the applicable percentage increase required under the Affordable Care Act. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under § 413.40. Therefore, for RNHCIs, the proposed update is the same as for children's and cancer hospitals, which is the percentage increase in the FY 2012 IPPS operating market basket, estimated to be 2.8 percent, without the reductions required under the Affordable Care Act.

The impact of the proposed update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with per-case cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that will not be reimbursed.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus 50 percent of the difference between its reasonable costs and 110 percent of the limit, not to exceed 110 percent of its limit. In addition, under the various provisions set forth in § 413.40, cancer and children's hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

VI. Quantitative Effects of the Proposed Policy Changes Under the IPPS for Operating Costs

A. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for operating costs of acute care hospitals. Updates to the capital payments to acute care hospitals are discussed in section VIII. of this Appendix. Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2012 operating payments would change by −0.5 percent compared to FY 2011, largely due to the documentation and coding adjustments and the applicable percentage increase applied to the IPPS rates. This amount reflects the proposed FY 2012 adjustments for documentation and coding and recoupment described in section II.D. of the preamble of this proposed rule: −3.15 percent for the IPPS national standardized amounts and −2.5 percent for the IPPS hospital-specific rates. The impacts do not illustrate changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes to each system. This section deals with proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available data to enable us to estimate the impacts on payments per case of certain proposed changes in this proposed rule. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented below are taken from the FY 2010 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use

various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2010 MedPAR file, we simulated payments under the operating IPPS given various combinations of payment parameters. As described above, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, or the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2012 are discussed in section VIII. of this Appendix.

We discuss the following proposed changes below:

- Effects of the application of the proposed documentation and coding adjustment and applicable percentage increase (including the proposed market basket update, the multifactor productivity adjustment and the applicable percentage reduction in accordance with the Affordable Care Act) to the standardized amount and hospital-specific rates.
- Effects of the proposed increase to the standardized amount and hospital-specific rates in light of D.C. Circuit's decision in *Cape Cod* v. *Sebelius,* 630 F.3d 203 (D.C. Cir. 2011).
- The effects of the proposed annual reclassification of diagnoses and procedures, full implementation of the MS–DRG system and 100 percent cost-based MS–DRG relative weights.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2008, compared to the FY 2007 wage data.
- The effects of the recalibration of the MS–DRG relative weights as required by section 1886(d)(4)(C) of the Act, including the wage and recalibration budget neutrality factors.
- The effects of the proposed geographic reclassifications by the MGCRB that will be effective in FY 2012.
- The effects of the rural floor with the application of the national budget neutrality factor applied to the wage index, as required by the Affordable Care Act.
- The effects of the expiration of applying an imputed floor to States that have no rural areas and to States that have rural areas but no IPPS hospitals are located in those areas.
- The effects of the frontier wage index provision that requires that hospitals located in States that qualify as frontier States cannot have a wage index less than 1.0. This provision is not budget neutral.
- The effects of section 505 of Pub. L. 108–173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.
- The total estimated change in payments based on the proposed FY 2012 policies relative to payments based on FY 2011 policies that include the applicable percentage increase of 1.5 percent (or 2.8 percent market basket update with a reduction of 1.2 percentage points for the multifactor productivity adjustment, and a 0.1 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the proposed FY 2012 changes, our analysis begins with a FY 2011 baseline simulation model using: the proposed FY 2012 applicable percentage increase of 1.5 percent and the proposed documentation and coding adjustment of −3.15 percent; the FY 2011 MS–DRG GROUPER (Version 28.0); the most current CBSA designations for hospitals based on OMB's MSA definitions; the FY 2011 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 through FY 2014, the update factor will include a reduction of 2.0 percentage points for any hospital that does not submit quality data in a form and manner and at a time specified by the Secretary. (Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act.) At the time that this impact was prepared, 56 hospitals did not receive the full market basket rate-of-increase for FY 2011 because they failed the quality data submission process or did not choose to participate. For purposes of the simulations shown below, we modeled the proposed payment changes for FY 2012 using a reduced update for these 56 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update factor for FY 2012.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2012 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each change.

Our final comparison illustrates the percent change in payments per case from FY 2011 to FY 2012. Three factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are proposing to update the standardized amounts for FY 2012 using an applicable percentage increase of 1.5 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.8 percent with a proposed reduction of 1.2 percentage points for the multifactor productivity adjustment and a 0.1 percentage point reduction as required under the Affordable Care Act. (Hospitals that fail to comply with the quality data submission requirements will receive a proposed update of −0.5 percent (this update includes the 2.0 percentage point reduction for failure to submit these data).) Under section 1886(b)(3)(B)(iv) of the Act, the proposed updates to the hospital-specific amounts for SCHs and for MDHs are also equal to the applicable percentage increase, or 1.5 percent. In addition, we are proposing to update the Puerto Rico-specific amount by an applicable percentage increase of 1.5 percent.

A second significant factor that affects the changes in hospitals' payments per case from FY 2011 to FY 2012 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2011 that are no longer reclassified in FY 2012. Conversely, payments may increase for hospitals not reclassified in FY 2011 that are reclassified in FY 2012.

A third significant factor is that we currently estimate that actual outlier payments during FY 2011 will be 4.9 percent of total MS–DRG payments. Our updated FY 2011 outlier estimate accounts for changes to the FY 2011 IPPS payments required under the Affordable Care Act. When the FY 2011 final rule was published, we projected FY 2011 outlier payments would be 5.1 percent of total MS–DRG plus outlier payments; the average standardized amounts were offset correspondingly. The effects of the lower than expected outlier payments during FY 2011 (as discussed in the Addendum to this proposed rule) are reflected in the analyses below comparing our current estimates of FY 2011 payments per case to estimated FY 2012 payments per case (with outlier payments projected to equal 5.1 percent of total MS–DRG payments).

B. Analysis of Table I

Table I displays the results of our analysis of the proposed changes for FY 2012. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,419 acute care hospitals included in the analysis.

The next four rows of Table I contain hospitals categorized according to their geographic location: all urban, which is further divided into large urban and other urban; and rural. There are 2,492 hospitals located in urban areas included in our analysis. Among these, there are 1,369 hospitals located in large urban areas (populations over 1 million), and 1,123 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 927 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The final groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2012 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban, large urban, other urban, and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have

implications for capital payments) are 2,514; 1,382; 1,132; and 905, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive DSH payments, or some combination of these two adjustments. There are 2,389 nonteaching hospitals in our analysis, 790 teaching hospitals with fewer than 100 residents, and 240 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next five rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs, RRCs, and MDHs). There were 175 RRCs, 320 SCHs, 195 MDHs, and 120 hospitals that are both SCHs and RRCs, and 18 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total patient days. These data were taken from the FY 2008 or FY 2007 Medicare cost reports.

The next two groupings concern the geographic reclassification status of hospitals. The first grouping displays all urban hospitals that were reclassified by the MGCRB for FY 2012. The second grouping shows the MGCRB rural reclassifications. The final category shows the impact of the proposed policy changes on the 19 cardiac hospitals.

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TABLE I.--IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2012

	Number of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	Proposed Cape Cod Adjustment[3] (3)	Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5)	Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Expiration of the Imputed Floor[9] (9)	Proposed Application of the Frontier Wage Index[10] (10)	Proposed FY 2012 Out-Migration Adjustment[11] (11)	Expiration of Section 508[12] (12)	All Proposed FY 2012 Changes[13] (13)
All Hospitals	3,419	-1.6	1.1	0	0	0	0	0	0	0	0	-0.2	-0.5
By Geographic Location:													
Urban hospitals	2,492	-1.6	1.1	0	0	0	-0.2	0	0	0	0	-0.2	-0.4
Large urban areas	1,369	-1.6	1.1	0	0	0	-0.3	0	0	0	0	-0.2	-0.4
Other urban areas	1,123	-1.6	1.1	0	0	0	-0.1	0.2	0	0.1	0	-0.2	-0.5
Rural hospitals	927	-1.3	1	0	-0.1	0	1.7	-0.2	0	0	0.1	0	-0.8
Bed Size (Urban):													
0-99 beds	634	-1.6	1.1	0.1	-0.1	-0.1	-0.5	0.2	0.1	0.1	0	-0.1	-0.3
100-199 beds	777	-1.6	1.1	0.1	0	0.1	0	0.3	0	0	0	-0.2	-0.4
200-299 beds	457	-1.6	1.1	0.1	0.2	0.2	-0.2	0	-0.1	0.1	0	-0.1	-0.4
300-499 beds	428	-1.6	1.1	0	-0.1	-0.1	-0.2	-0.1	0	0.1	0	-0.2	-0.7
500 or more beds	196	-1.6	1.1	-0.1	0.1	0	-0.3	0.1	0	0	0	-0.2	-0.2
Bed Size (Rural):													
0-49 beds	317	-1.3	1	0.1	0.1	0.1	0.6	-0.2	0	0.1	0.2	0	-1.2

	Number of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	Proposed Cape Cod Adjustment[3] (3)	Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5)	Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Expiration of the Imputed Floor[9] (9)	Proposed Application of the Frontier Wage Index[10] (10)	Proposed FY 2012 Out-Migration Adjustment[11] (11)	Expiration of Section 508[12] (12)	All Proposed FY 2012 Changes[13] (13)
50-99 beds	351	-1.3	1	0	-0.1	0	0.7	-0.2	0	0	0.1	0	-1
100-149 beds	153	-1.4	1	0	-0.1	-0.1	2.3	-0.2	0.1	0	0	0	-0.7
150-199 beds	60	-1.4	1	0	-0.1	-0.1	2.5	-0.2	0.1	0.1	0	0	-0.6
200 or more beds	46	-1.4	1	0	-0.1	-0.1	2.6	-0.2	0	0	0	0	-0.5
Urban by Region:													
New England	120	-1.6	1.1	0.1	0.1	0.2	0.9	5	0.1	0	0	-0.2	3.6
Middle Atlantic	320	-1.6	1.1	0	0.3	0.3	0.3	-0.4	-0.4	0	0	-0.4	-0.9
South Atlantic	379	-1.6	1.1	0	-0.3	-0.3	-0.4	-0.3	0.1	0	0	0	-0.8
East North Central	401	-1.6	1.1	0	-0.4	-0.3	-0.3	-0.3	0.1	0	0	-0.4	-1.2
East South Central	153	-1.6	1.1	0	-0.3	-0.3	-0.4	-0.2	0.1	0	0	0	-1
West North Central	168	-1.6	1.1	0	0.3	0.2	-0.6	-0.3	0.1	0.5	0	0	-0.1
West South Central	365	-1.6	1.1	0	0.4	0.4	-0.6	-0.3	0.1	0	0	0	-0.1
Mountain	159	-1.5	1.1	-0.1	0	-0.1	-0.4	-0.1	0.1	0.2	0	0	-0.5
Pacific	377	-1.6	1.1	0	0.2	0.2	-0.2	-0.2	0.1	0	0	-0.1	-0.3
Puerto Rico	50	-1.1	0.9	0.1	0.3	0.2	-0.8	0.1	0.1	0	0	0	0.2

	Number of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	Proposed Cape Cod Adjustment[3] (3)	Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5)	Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Expiration of the Imputed Floor[9] (9)	Proposed Application of the Frontier Wage Index[10] (10)	Proposed FY 2012 Out-Migration Adjustment[11] (11)	Expiration of Section 508[12] (12)	All Proposed FY 2012 Changes[13] (13)
Rural by Region:													
New England	23	-1.3	1	-0.1	0.8	0.7	1.2	-0.2	0	0	0	0	-0.9
Middle Atlantic	69	-1.3	1	0	-0.1	-0.1	1.4	-0.2	0	0	0	-0.1	-0.3
South Atlantic	165	-1.4	1	0	-0.2	-0.2	2.2	-0.2	0.1	0	0	0	-0.6
East North Central	120	-1.3	1	0	-0.1	-0.1	1.1	-0.2	0	0	0.1	0	-0.5
East South Central	171	-1.5	1.1	0.1	-0.5	-0.3	2.6	-0.3	0.1	0	0.2	-0.1	-1.6
West North Central	99	-1.1	0.9	-0.1	0.1	0	0.7	-0.1	0	0.1	0	-0.1	-0.2
West South Central	184	-1.5	1.1	0.1	0.4	0.4	2.4	-0.3	0.1	0	0.1	0	-1.2
Mountain	66	-1.2	1	0.1	0.1	0.2	0.5	-0.1	0	0.6	0	0	-0.5
Pacific	29	-1.2	1	0	-0.4	-0.4	1.7	-0.1	0	0	0	0	-0.4
Puerto Rico	1	-1	0.9	-0.2	0.7	0.3	-0.8	-0.3	0	0	0	0	0.3
By Payment Classification:													
Urban hospitals	2,514	-1.6	1.1	0	0	0	-0.2	0	0	0	0	-0.2	-0.4
Large urban areas	1,382	-1.6	1.1	0	0	0	-0.3	0	0	0	0	-0.2	-0.4
Other urban areas	1,132	-1.6	1.1	0	0	0	0	0.1	0	0.1	0	-0.2	-0.5
Rural areas	905	-1.3	1	0	-0.1	-0.1	1.5	-0.2	0	0	0.1	0	-0.8

	Number of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed Cape Cod Adjustment[3] (3)	Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5)	Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Expiration of the Imputed Floor[9] (9)	Proposed Application of the Frontier Wage Index[10] (10)	Proposed FY 2012 Out-Migration Adjustment[11] (11)	Expiration of Section 508[12] (12)	All Proposed FY 2012 Changes[13] (13)
Teaching Status:													
Nonteaching	2,389	-1.5	1.1	0.1	0	0	0.2	0	0	0	0	-0.1	-0.5
Fewer than 100 residents	790	-1.6	1.1	0	0	0	-0.2	-0.1	-0.1	0.1	0	-0.1	-0.6
100 or more residents	240	-1.6	1.1	-0.1	0.1	0	-0.2	0.1	0	0	0	-0.3	-0.4
Urban DSH:													
Non-DSH	738	-1.6	1.1	0	-0.1	-0.1	0	0	-0.2	0	0	-0.3	-0.9
100 or more beds	1,543	-1.6	1.1	0	0	0	-0.2	0	0	0	0	-0.1	-0.4
Less than 100 beds	339	-1.6	1.1	0.2	-0.3	-0.1	-0.2	0.2	0.1	0.1	0	-0.1	-0.4
Rural DSH:													
SCH	416	-1.2	1	0	0	0	0.2	-0.1	0	0	0.1	0	-1.5
RRC	222	-1.4	1	0	-0.1	-0.1	2.5	-0.2	0.1	0	0	0	-0.5
100 or more beds	28	-1.6	1.1	0.1	-0.3	-0.1	0.5	-0.3	0.1	0	0.3	-0.3	-1.2
Less than 100 beds	133	-1.6	1.1	0.2	-0.1	0.2	1.4	-0.4	0.1	0	0.4	-0.1	-0.6
Urban teaching and DSH:													
Both teaching and DSH	825	-1.6	1.1	0	0	0	-0.3	0	0	0.1	0	-0.2	-0.4
Teaching and no DSH	144	-1.6	1.1	-0.1	-0.1	-0.2	0.2	0.1	-0.3	0	0	-0.4	-1

	Number of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	Proposed Cape Cod Adjustment[3] (3)	Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5)	Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Expiration of the Imputed Floor[9] (9)	Proposed Application of the Frontier Wage Index[10] (10)	Proposed FY 2012 Out-Migration Adjustment[11] (11)	Expiration of Section 508[12] (12)	All Proposed FY 2012 Changes[13] (13)
No teaching and DSH	1,057	-1.6	1.1	0.1	0	0.1	0	0.1	0.1	0	0	0	-0.2
No teaching and no DSH	488	-1.6	1.1	0	-0.1	-0.1	-0.3	-0.2	-0.1	0	0	-0.2	-0.8
Special Hospital Types:													
RRC	175	-1.6	1.1	0	-0.2	-0.1	3.1	-0.3	0.1	0.1	0	-0.2	-0.8
SCH	320	-1.1	0.9	-0.1	0	-0.1	0.2	-0.1	0	0	0	0	-1.4
MDH	195	-1.4	1	0	0	0.1	0.2	-0.1	0	0	0.1	0	-0.4
SCH and RRC	120	-1.1	0.9	-0.1	0	-0.1	0.8	-0.1	0	0	0	0	-0.3
MDH and RRC	18	-1.1	1	-0.1	0.1	0	0.5	-0.1	0	0	0	0	-0.3
Type of Ownership:													
Voluntary	1,991	-1.6	1.1	0	0	0	0	0.1	0	0.1	0	-0.2	-0.4
Proprietary	850	-1.6	1.1	0.1	0.1	0.1	-0.1	-0.2	0.1	0	0	-0.1	-0.5
Government	574	-1.5	1.1	0	-0.1	-0.1	-0.1	-0.2	0.1	0	0	-0.1	-0.7
Medicare Utilization as a Percent of Inpatient Days:													
0-25	359	-1.5	1.1	-0.1	0	-0.1	-0.3	-0.3	0.1	0	0	0	-0.4
25-50	1,703	-1.6	1.1	0	0	0	-0.2	0	0	0.1	0	-0.2	-0.4

	Number of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	Proposed Cape Cod Adjustment[3] (3)	Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5)	Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Expiration of the Imputed Floor[9] (9)	Proposed Application of the Frontier Wage Index[10] (10)	Proposed FY 2012 Out-Migration Adjustment[11] (11)	Expiration of Section 508[12] (12)	All Proposed FY 2012 Changes[13] (13)
50-65	1,089	-1.5	1.1	0	-0.1	0	0.7	0.1	0	0	0	-0.2	-0.7
Over 65	195	-1.5	1.1	0.1	-0.1	0.1	0.5	0	-0.3	0	0	-0.3	-0.6
FY 2012 Reclassifications by the Medicare Geographic Classification Review Board:													
All Reclassified Hospitals	805	-1.5	1.1	0	-0.1	0	1.9	0.3	0	0	0	-0.4	-0.3
Non-Reclassified Hospitals	2,614	-1.6	1.1	0	0	0	-0.7	-0.1	0	0.1	0	-0.1	-0.5
Urban Hospitals Reclassified	469	-1.6	1.1	0	-0.1	0	1.6	0.5	0	0	0	-0.6	-0.2
Urban Nonreclassified Hospitals, FY 2012:	1,990	-1.6	1.1	0	0	0	-0.7	-0.1	0	0.1	0	-0.1	-0.5
All Rural Hospitals Reclassified FY 2012:	336	-1.4	1	0	-0.1	-0.1	2.7	-0.2	0.1	0	0	0	-0.6
Rural Nonreclassified Hospitals FY 2012:	529	-1.3	1	0	0	0	-0.3	-0.2	0	0.1	0.2	-0.1	-1.2

	Number of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	Proposed Cape Cod Adjustment[3] (3)	Proposed FY 2012 Weights and DRG Changes with Application of Recalibration Budget Neutrality[4] (4)	Proposed FY 2012 Wage Data with Application of Wage Budget Neutrality[5] (5)	Proposed FY 2012 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[6] (6)	FY 2012 MGCRB Reclassifications[7] (7)	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality[8] (8)	Expiration of the Imputed Floor[9] (9)	Proposed Application of the Frontier Wage Index[10] (10)	Proposed FY 2012 Out-Migration Adjustment[11] (11)	Expiration of Section 508[12] (12)	All Proposed FY 2012 Changes[13] (13)
All Section 401 Reclassified Hospitals:	40	-1.1	0.9	-0.1	0	-0.1	-0.8	0.2	0	0	0	0	-0.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	63	-1.4	1	0	0	0	2.8	-0.2	0.1	0	0	0	-0.9
Specialty Hospitals													
Cardiac specialty Hospitals	19	-1.6	1.1	-0.1	0	-0.1	-0.8	-0.4	0.1	0.2	0	0	-0.6

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2010, and hospital cost report data are from reporting periods beginning in FY 2009 and FY 2008.

[2] This column displays the payment impact of the proposed hospital rate update and documentation and coding adjustment including the 1.5 percent adjustment to the national standardized amount (the 2.8 percent market basket update reduced by the proposed 1.2 percentage points for the multifactor productivity adjustment and the 0.1 percentage point reduction under the Affordable Care Act) and the -3.15 percent documentation and coding adjustment to the national standardized amount and the proposed -2.5 documentation and coding adjustment to the hospital-specific rate.

[3] This column displays the payment impact of the proposed 1.1 percent adjustment to the national standardized amount and the 0.9 percent adjustment to the hospital-specific rate in light of the decision in Cape Cod v. Sebelius.

[4] This column displays the payment impact of the proposed changes to the Version 29.0 GROUPER and the recalibration of the MS-DRG weights based on FY 2010 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.998418, in accordance with section 1886(d)(4)(C)(iii) of the Act.

[5.] This column displays the payment impact of the proposed update to wage index data using FY 2008 cost report data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and will be calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000113.

[6] This column displays the combined payment impact of the proposed changes in Columns 4 through 5 and the cumulative budget neutrality factor for MS-DRG and wage changes in accordance with section 1886(d)(4)(C)(iii) of the Act and section 1886(d)(3)(E) of the Act. The cumulative wage and recalibration budget neutrality factor of 0.998532 is the product of the wage budget neutrality factor and the recalibration budget neutrality factor.

[7.] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2012 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2012. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.991528.

[8] This column displays the effects of the rural floor, including the Affordable Care Act requirement that the floor budget neutrality is at a 100 percent national level adjustment. The rural floor budget neutrality factor is 0.993834.

[9.] This column displays the effects of the expiration of the imputed floor, finalized in the FY 2009 IPPS rule (73 FR 48570 through 48574 and 48584).

[10/] This column shows the impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0.

[11.] This column displays the impact of section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.

[12.] This column displays the impact of the expiration of section 508 of the MMA as extended by the MMEA, a non-budget neutral reclassification provision.

[13] This column shows the proposed changes in payments from FY 2011 to FY 2012. It reflects the impact of the proposed FY 2012 hospital update, the proposed reductions due to the documentation and coding effect and the proposed adjustment in light of the decision in Cape Cod v. Sebelius. The proposed FY 2012 documentation and coding adjustment is -3.15 percent to the IPPS standardized amounts and -2.5 percent to the hospital-specific rates. It also reflects changes in hospitals' reclassification status in FY 2012 compared to FY 2011. It incorporates all of the proposed changes displayed in Columns 2, 3, 6, 7, 8, 10, 11 and 12 (the changes displayed in Columns 4 and 5 are included in Column 6). The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.

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1. Effects of the Proposed Hospital Update and Documentation and Coding Adjustment (Column 2)

As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed hospital update including the 2.8 percent market basket update, the reduction of 1.2 percentage points for the multifactor productivity adjustment and the 0.1 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the proposed FY 2012 documentation and coding adjustment of −3.15 percent on the national standardized amount and the proposed −2.5 percent documentation and coding adjustment on the hospital-specific rates. As a result, we are proposing to apply a −1.65 percent adjustment to the national standardized amount and −1.0 percent adjustment to the hospital specific rate. Overall, hospitals will experience a −1.6 percent decrease in payments due to the effects of the hospital update and documentation and coding adjustment on the national standardized amount. Hospital categories that experience less than a 1.6 percent decrease in payments have hospitals that are paid under the hospital-specific rate, which is reduced by 1.0 percent. In addition, Puerto Rico hospitals will experience a −1.0 percent decrease in payments, a smaller decrease than average, because we are not proposing any documentation and coding adjustment to the Puerto Rico-specific rate, which is 25 percent of Puerto Rico's payment rate.

2. Effects of the Proposed Adjustment to the Standardized Amount for Cape Cod Hospital v. Sebelius (Column 3)

Column 3 shows the impact of the proposed 1.1 percent adjustment to the national standardized amount and the proposed 0.9 percent adjustment to the hospital-specific rate in light of the decision in *Cape Cod Hospital* v. *Sebelius,* as discussed in section II. of the Addendum to this proposed rule.

Overall, hospitals will experience a 1.1 percent increase in payments due to the effects of the adjustment on the national standardized amount. Hospital categories that experience less than a 1.1 percent increase in payments include hospitals that are paid under the hospital-specific rate, which we are proposing to increase by 0.9 percent. Rural hospitals will experience a 1.0 percent increase in payments because many rural hospitals are paid under the hospital-specific rate, which we are proposing to increase by 0.9 percent.

3. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights with Recalibration Budget Neutrality (Column 4)

Column 4 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are calculating a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2012 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2012, the proposed MS–DRGs are calculated using the FY 2010 MedPAR data grouped to the Version 29.0 (FY 2012) MS–DRGs. The methods of calculating the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.H. of the preamble of this proposed rule.

The "All Hospitals" line in Column 4 indicates that proposed changes due to MS–DRGs and relative weights will result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 0.998413 on to the standardized amount. The changes in payments due to the proposed MS–DRGs, relative weights and GROUPER are modest with no hospital category seeing an increase or decrease of more than 0.2 percent.

4. Effects of Proposed Wage Index Changes (Column 5)

Column 5 shows the impact of updated wage data with the application of the wage budget neutrality factor. Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2012 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2007 and before October 1, 2008. The estimated impact of the updated wage data and labor share on hospital payments is isolated in Column 5 by holding the other payment parameters constant in this simulation. That is, Column 5 shows the percentage change in payments when going from a model using the FY 2011 wage index, based on FY 2007 wage data, the current labor-related share and having a 100-percent occupational mix adjustment applied, to a model using the FY 2012 pre-reclassification wage index with the labor-related share, also having a 100-percent occupational mix adjustment applied, based on FY 2008 wage data (while holding other payment parameters such as use of the Version 29.0 MS–DRG GROUPER constant). The occupational mix adjustment is based on the 2007–2008 occupational mix survey.

In addition, the column shows the impact of the application of wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2012, we are calculating the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share are budget neutral without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The proposed wage budget neutrality factor is 1.000113, and the overall payment change is 0 percent.

Column 5 shows the impacts of updating the wage data using FY 2008 cost reports. Overall, the new wage data will lead to a 0.0 percent change for all hospitals before being combined with the wage budget neutrality adjustment shown in Column 5. Among the regions, the largest increase is in the rural New England region, which experiences a 0.8 percent increase due to increases in the wage index among rural Connecticut and rural Massachusetts hospitals. The largest decline from updating the wage data is seen in the rural East South Central region (−0.5 percent decrease).

In looking at the wage data itself, the national average hourly wage increased 3.4 percent compared to FY 2011. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 3.4 percent increase in average hourly wage. Of the 3,424 hospitals with wage data for both FYs 2011 and 2012, 1,681, or 49.1 percent, experienced an average hourly wage increase of 3.4 percent or more.

The following chart compares the shifts in proposed wage index values for hospitals for FY 2012 relative to FY 2011. Among urban hospitals, 37 will experience an increase of more than 5 percent and less than 10 percent and 5 will experience an increase of more than 10 percent. Among rural hospitals, 1 will experience an increase of more than 5 percent and less than 10 percent, and none will experience an increase of more than 10 percent. However, 915 rural hospitals will experience increases or decreases of less than 5 percent, while 2,397 urban hospitals will experience increases or decreases of less than 5 percent. Fifty-six urban hospitals will experience decreases in their wage index values of more than 5 percent and less than 10 percent. Sixteen urban hospitals will experience decreases in their wage index values of greater than 10 percent. One rural hospital will experience a decrease of more than 10 percent. Ten rural hospitals will experience decreases in their wage index values of greater than 5 percent but less than 10 percent. These figures reflect changes in the wage index which is an adjustment to either 68.8 percent or 62 percent of the labor share of a hospital's standardized amount, depending upon whether its wage index is greater than 1.0 or less than or equal to 1.0. Therefore, these figures illustrate a somewhat larger change in the wage index than will occur to the hospital's total payment.

The following chart shows the projected impact for urban and rural hospitals.

Percentage Change in Area Wage Index Values	Number of Hospitals	
	Urban	Rural
Increase more than 10 percent	5	0
Increase more than 5 percent and less than 10 percent	37	1
Increase or decrease less than 5 percent	2,397	915
Decrease more than 5 percent and less than 10 percent	56	10
Decrease more than 10 percent	16	1

5. Combined Effects of the Proposed MS–DRG and Wage Index Changes (Column 6)

Section 1886(d)(4)(C)(iii) of the Act requires that changes to MS–DRG reclassifications and the relative weights cannot increase or decrease aggregate payments. In addition, section 1886(d)(3)(E) of the Act specifies that any updates or adjustments to the wage index are to be budget neutral. We computed a proposed wage budget neutrality factor of 1.000113, and a proposed recalibration budget neutrality factor of 0.998419 (which is applied to the Puerto Rico-specific standardized amount and the hospital-specific rates). The product of the two proposed budget neutrality factors is the proposed cumulative wage and recalibration budget neutrality factor. The proposed cumulative wage and recalibration budget neutrality adjustment is 0.998532, or approximately −0.15 percent, which is applied to the national standardized amounts. Because the wage budget neutrality and the recalibration budget neutrality are calculated under different methodologies according to the statute, when the two budget neutralities are combined and applied to the standardized amount, the overall payment impact is not necessarily budget neutral. However, in this proposed rule, we are estimating that the changes in the MS–DRG relative weights and updated wage data with wage and budget neutrality applied will result in a 0.0 change in payments.

We estimate that the combined impact of the proposed changes to the relative weights and MS–DRGs and the proposed updated wage data with budget neutrality applied will result in no change in payments for urban or rural hospitals. Urban West South Central hospitals would experience a 0.4 percent increase in payments due to increases in their wages compared to the national average, while the urban East South Central and East North Central area would experience a −0.3 decrease in payments because of below average increases in wages. Among the rural hospital categories, rural New England hospitals would experience the greatest increase in payment (0.7 percent) primarily due to above average increases in the wage data, while the rural Pacific area would experience a 0.4 percent decrease in payments due to decreases in the wage data.

6. Effects of MGCRB Reclassifications (Column 7)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on other bases than where they are geographically located). The changes in Column 7 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2012 which affect hospitals' wage index area assignments.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from publication of the IPPS rule in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for the purposes of this impact analysis, we are applying an adjustment of 0.991528 to ensure that the effects of the section 1886(d)(10) reclassifications are budget neutral (section II.A. of the Addendum to this proposed rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that geographic reclassification will increase payments to rural hospitals by an average of 1.7 percent. By region, all the rural hospital categories, with the exception of the one rural Puerto Rico hospital, will experience increases in payments due to MGCRB reclassification. Rural hospitals in the East South Central region will experience a 2.6 percent increase in payments and rural hospitals in the Mountain region will experience a 0.5 percent increase in payments. Urban hospitals in New England and the Middle Atlantic will experience an increase in payments of 0.9 percent and 0.3 percent, respectively, largely due to reclassifications of hospitals in Connecticut and New Jersey.

Table 9A listed in section VI. of the Addendum to this proposed rule and available via the Internet reflects the approved reclassifications for FY 2012.

7. Effects of the Rural Floor, Including Application of National Budget Neutrality (Column 8)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FY 2011 IPPS/LTCH PPS final rule and this proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. Beginning with FY 2008, we apply a uniform budget neutrality adjustment is applied to the wage index. For FY 2012 (and in FY 2011), the Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index, nationally. The proposed FY 2012 rural floor budget neutrality factor applied to the wage index is 0.993834, which would reduce wage indexes by −0.62 percent.

Column 8 shows the projected impact of the rural floor with the national rural floor budget neutrality factor applied to the wage index. The column compares the post-reclassification FY 2012 wage index of providers before the rural floor adjustment and the post-reclassification FY 2012 wage index of providers with the rural floor adjustment. Only urban hospitals can benefit from the rural floor provision. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) experience a decrease in payments due to the budget neutrality adjustment applied nationally to their wage index.

We project that, in aggregate, rural hospitals will experience a −0.2 percent decrease in payments as a result of the application of rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in other urban areas (populations of 1 million or fewer) will experience a 0.2 percent increase in payments because those providers benefit from the rural floor. Urban hospitals in the New England region can expect a 5.0 percent increase in payments primarily due to the application of the rural floor in Massachusetts and the applicable national rural floor budget neutrality as required by the Affordable Care Act. All 60 urban providers in Massachusetts are expected to receive the rural floor wage index of 1.3614. During most past years, there have been no IPPS hospitals located in rural areas in Massachusetts. There was one urban IPPS hospital that was reclassified to rural Massachusetts (under section 1886(d)(8)(E) of the Act) which established the Massachusetts rural floor, but the wage index resulting from that hospital's data was not high enough for any urban hospital to benefit from the rural floor policy. However, beginning with the FY 2012 wage index, the rural floor for the State

is established by the conversion of a CAH to an IPPS hospital that is geographically located in rural Massachusetts. Massachusetts hospitals can expect approximately an 8-percent increase in IPPS payments due to the application of rural floor.

Urban Puerto Rico hospitals are expected to experience a 0.1 percent increase in payments as a result of the application of a Puerto Rico rural floor. Similar to Massachusetts, this is the first year in which urban Puerto Rico hospitals will receive a rural floor as a result of a new IPPS hospital located in rural Puerto Rico setting a rural floor. We are proposing to apply a rural floor budget neutrality factor to the Puerto Rico-specific wage index of 0.989226 or 1.1 percent. The Puerto Rico-specific wage index adjusts the Puerto Rico-specific standardized amount, which represents 25 percent of payments to Puerto Rico hospitals.

8. Effects of the Expiration of the Imputed Floor (Column 9)

As discussed in section III.F.2. of the preamble of this proposed rule, the imputed floor, which is budget neutral, is set to expire with the FY 2011 wage index, and we are not proposing to extend it.

Column 9 shows the effects of the expiration of the imputed floor. This column compares payments that would have been made if the imputed floor were still in place to payments that are estimated to be made with only the rural floor. There are 39 hospitals in New Jersey that are affected by the expiration of the imputed floor. Therefore, only urban providers in the Middle Atlantic Region (New Jersey) will experience a decrease by 0.4 percent, from the imputed floor no longer being applied in that State. Hospitals in other regional categories will experience an increase in payments as they will no longer have payments reduced because of the imputed floor to ensure budget neutrality.

9. Effects of the Proposed Application of the Frontier Wage Index (Column 10)

Section 10324(a) of Affordable Care Act requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in "frontier States." The term "frontier States" is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, five States (Montana, North Dakota, Nevada, South Dakota, and Wyoming) are considered frontier States and 47 hospitals located in those States will receive a frontier wage index of 1.0. This provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $48 million.

Urban hospitals located in the West North Central region and urban hospitals located in the Mountain region will experience an increase in payments by 0.5 percent and 0.2 percent, respectively because many of the hospitals located in this region are frontier hospitals. Similarly, rural hospitals located in the Mountain region and rural hospitals in the West North Central region will experience an increase in payments by 0.6 percent and 0.1 percent, respectively.

10. Effects of the Proposed Wage Index Adjustment for Out-Migration (Column 11)

Section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. Overall, rural hospitals will experience a 0.1 percent increase in payments as a result of the outmigration adjustment. Rural providers with less than 50 beds will experience a 0.2 percent increase in payments in FY 2012. We included these additional payments to providers in the impact table shown above, and we estimate the impact of these providers receiving the out-migration increase to be approximately $14 million.

11. Effects of the Expiration of Section 508 (Column 12)

Column 12 shows our estimate of the changes in payments due to the expiration of section 508, a non-budget neutral reclassification provision, applied under the MMEA. Because this provision is not budget neutral, the expiration of this reclassification provision results in a −0.2 percent decrease in payments, overall. Section 508 hospitals are generally urban hospitals, resulting in a −0.2 percent decrease in payments among the urban hospital category and a 0.0 percent change in payments among rural hospitals. Urban New England and Urban Middle Atlantic regions will experience a decrease in payments of −0.2 percent and −0.4 percent respectively because many section 508 hospitals are located in those regions. Urban teaching hospitals that do not receive DSH will experience a −0.3 percent decrease in payments due to the expiration of section 508.

12. Effects of All Proposed FY 2012 Changes (Column 13)

Column 13 shows our estimate of the changes in payments per discharge from FY 2011 and FY 2012, resulting from all proposed changes reflected in this proposed rule for FY 2012. It includes combined effects of the previous columns in the table.

The average decrease in payments under the IPPS for all hospitals is approximately −0.5 percent. As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed FY 2012 documentation and coding adjustment of −3.15 percent on the national standardized amount and −2.5 percent on the hospital-specific rates. In addition, this column includes the proposed annual hospital update of 1.5 percent to the national standardized amount. This annual hospital update includes the 2.8 percent market basket update, the reduction of −1.2 percentage points for the multifactor productivity adjustment, and the −0.1 percentage point reduction under section 3401 of the Affordable Care Act. As described in Column 2, the proposed annual hospital update, combined with the proposed documentation and coding adjustment, results in a −1.6 percent decrease in payments in FY 2012 relative to FY 2011. As described in Column 3, the proposed 1.1 percent adjustment to the national standardized amount and the proposed 0.9 percent adjustment to the hospital specific rate in light of a recent court decision related to rural floor budget neutrality results in a 1.1 percent increase in payments in FY 2012 relative to FY 2011. In addition, column 12 describes a −0.2 percent decrease in payments due to the expiration of section 508 reclassifications that had been extended for FY 2011 under the MMEA. Section 508 was not a budget-neutral provision. There might also be interactive effects among the various factors comprising the payment system that we are not able to isolate. For these reasons, the values in Column 13 may not equal the sum of the percentage changes described above.

The overall change in payments per discharge for hospitals paid under the IPPS in FY 2012 is estimated to decrease by −0.5 percent. The payment decreases among the hospital categories are largely attributed to the proposed documentation and coding adjustments. Hospitals in urban areas would experience an estimated −0.4 percent decrease in payments per discharge in FY 2012 compared to FY 2011. Hospital payments per discharge in rural areas are estimated to decrease by −0.8 percent in FY 2012 as compared to FY 2011.

Among urban census divisions, the largest estimated payment decreases will be 1.2 percent in the East North Central region because many of the urban providers in this region had benefited from section 508 reclassifications in FY 2011 that have expired for FY 2012. Urban Middle Atlantic providers will experience a −0.9 percent decrease in payments due to the expiration of the imputed floor that had previously benefited urban hospitals in this region. Urban hospitals in the New England will see the largest payment increases (3.6 percent) because the Massachusetts hospitals are benefitting from the rural floor in their State. Furthermore, urban Puerto Rico hospitals will experience a 0.2 percent increase in payments due to the application of the rural floor.

Among the rural regions, the providers in the East South Central region will experience the largest decrease in payments of −1.6 percent due to decreases in wage data. Rural hospitals in the West North Central region will experience a decrease in payments by −0.2 percent, which is better than average, because the rural providers in this region benefit from MGCRB reclassification and the frontier State wage index provision, implemented under the Affordable Care Act.

Among special categories of hospitals, MDHs will receive an estimated payment decrease of −0.4 percent. MDHs are paid the higher of the IPPS rate based on the national standardized amount, that is, the Federal rate, or, if the hospital-specific rate exceeds

the Federal rate, the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate. MDHs will experience a decrease in payments because of the proposed documentation and coding adjustments applied to both the Federal rate and the hospital-specific rate. SCHs are paid the higher of their Federal rate and the hospital-specific rate. Overall, SCHs will experience an estimated decrease in payments by −1.4 percent due to the proposed documentation and coding adjustments to the national standardized amount and the hospital-specific rates.

Rural hospitals reclassified for FY 2012 are anticipated to receive a −0.6 percent payment decrease, and rural hospitals that are not reclassifying are estimated to receive a payment decrease of −1.2 percent. Urban reclassified hospitals will experience payment decreases better than average at −0.2 percent due to the benefits under MGCRB reclassification and the rural floor. Urban non-reclassified hospitals will experience a payment decrease of −0.5 percent.

Cardiac hospitals are expected to experience a payment decrease of 0.6 percent in FY 2012 relative to FY 2011.

C. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2012 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2011 with the proposed payments per discharge for FY 2012, as calculated under our models. Thus, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 13 of Table I.

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TABLE II.--IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2012 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of Hospitals	Average FY 2011 Payment Per Discharge (2)	Average Proposed FY 2012 Payment Per Discharge (3)	All Proposed FY 2012 Changes (4)
All hospitals	3,419	$10,257	$10,209	-0.5
By Geographic Location:				
Urban hospitals	2,492	$10,667	$10,620	-0.4
Large urban areas (populations over 1 million)	1,369	$11,249	$11,203	-0.4
Other urban areas (populations of 1 million or fewer)	1,123	$9,950	$9,904	-0.5
Rural hospitals	927	$7,656	$7,595	-0.8
Bed Size (Urban):				
0-99 beds	634	$8,173	$8,149	-0.3
100-199 beds	777	$9,004	$8,970	-0.4
200-299 beds	457	$9,814	$9,777	-0.4
300-499 beds	428	$10,971	$10,894	-0.7
500 or more beds	196	$13,208	$13,176	-0.2
Bed Size (Rural):				
0-49 beds	317	$6,173	$6,101	-1.2
50-99 beds	351	$7,134	$7,061	-1
100-149 beds	153	$7,545	$7,491	-0.7
150-199 beds	60	$8,235	$8,188	-0.6
200 or more beds	46	$9,485	$9,434	-0.5
Urban by Region:				
New England	120	$11,138	$11,544	3.6
Middle Atlantic	320	$11,788	$11,679	-0.9
South Atlantic	379	$9,814	$9,736	-0.8
East North Central	401	$10,051	$9,930	-1.2
East South Central	153	$9,502	$9,403	-1
West North Central	168	$10,260	$10,245	-0.1
West South Central	365	$10,006	$9,999	-0.1
Mountain	159	$10,815	$10,763	-0.5
Pacific	377	$13,104	$13,059	-0.3
Puerto Rico	50	$5,284	$5,297	0.2
Rural by Region:				
New England	23	$10,176	$10,080	-0.9
Middle Atlantic	69	$8,040	$8,015	-0.3
South Atlantic	165	$7,363	$7,316	-0.6
East North Central	120	$7,963	$7,920	-0.5
East South Central	171	$7,023	$6,907	-1.6
West North Central	99	$8,136	$8,123	-0.2
West South Central	184	$6,729	$6,645	-1.2
Mountain	66	$8,500	$8,460	-0.5

	Number of Hospitals	Average FY 2011 Payment Per Discharge (2)	Average Proposed FY 2012 Payment Per Discharge (3)	All Proposed FY 2012 Changes (4)
Pacific	29	$10,326	$10,281	-0.4
Puerto Rico	1	$2,280	$2,287	0.3
By Payment Classification:				
Urban hospitals	2,514	$10,652	$10,605	-0.4
Large urban areas (populations over 1 million)	1,382	$11,234	$11,187	-0.4
Other urban areas (populations of 1 million or fewer)	1,132	$9,930	$9,885	-0.5
Rural areas	905	$7,732	$7,672	-0.8
Teaching Status:				
Non-teaching	2,389	$8,591	$8,551	-0.5
Fewer than 100 Residents	790	$10,161	$10,103	-0.6
100 or more Residents	240	$15,094	$15,041	-0.4
Urban DSH:				
Non-DSH	738	$8,955	$8,879	-0.9
100 or more beds	1,543	$11,154	$11,114	-0.4
Less than 100 beds	339	$7,615	$7,586	-0.4
Rural DSH:				
SCH	416	$7,120	$7,015	-1.5
RRC	222	$8,466	$8,427	-0.5
100 or more beds	28	$6,290	$6,213	-1.2
Less than 100 beds	133	$5,962	$5,923	-0.6
Urban teaching and DSH:				
Both teaching and DSH	825	$12,198	$12,148	-0.4
Teaching and no DSH	144	$9,863	$9,766	-1
No teaching and DSH	1,057	$9,116	$9,095	-0.2
No teaching and no DSH	488	$8,533	$8,463	-0.8
Rural Hospital Types:				
RRC	175	$8,557	$8,486	-0.8
SCH	320	$8,157	$8,039	-1.4
MDH	195	$6,472	$6,447	-0.4
SCH and RRC	120	$9,414	$9,390	-0.3
MDH and RRC	18	$8,466	$8,442	-0.3
Type of Ownership:				
Voluntary	1,991	$10,381	$10,336	-0.4
Proprietary	850	$9,131	$9,085	-0.5
Government	574	$10,958	$10,885	-0.7
Medicare Utilization as a Percent of Inpatient Days:				
0-25	359	$14,311	$14,257	-0.4
25-50	1,703	$10,902	$10,857	-0.4
50-65	1,089	$8,503	$8,446	-0.7
Over 65	195	$7,426	$7,381	-0.6

	Number of Hospitals	Average FY 2011 Payment Per Discharge (2)	Average Proposed FY 2012 Payment Per Discharge (3)	All Proposed FY 2012 Changes (4)
Hospitals Reclassified by the Medicare Geographic Classification Review Board: FY 2012 Reclassifications:				
All Reclassified Hospitals FY 2012	805	$10,011	$9,979	-0.3
All Non-Reclassified Hospitals FY 2012	2,614	$10,346	$10,292	-0.5
Urban Reclassified Hospitals FY 2012:	469	$10,735	$10,709	-0.2
Urban Non-reclassified Hospitals FY 2012	1,990	$10,665	$10,613	-0.5
Rural Reclassified Hospitals FY 2012	336	$8,246	$8,199	-0.6
Rural Nonreclassified Hospitals FY 2012:	529	$6,819	$6,738	-1.2
All Section 401 Reclassified Hospitals:	40	$8,594	$8,537	-0.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	63	$7,260	$7,193	-0.9
Specialty Hospitals				
Cardiac Hospitals	19	$11,159	$11,093	-0.6

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VII. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed above that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes. Our estimates of the likely impacts associated with these other proposed changes are discussed below.

A. Effects of Proposed Policy on HACs, Including Infections

In section II.F. of the preamble of this proposed rule, we discuss our implementation of section 1886(d)(4)(D) of the Act, which requires the Secretary to identify conditions that are: (1) High cost, high volume, or both; (2) result in the assignment of a case to an MS–DRG that has a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission, unless, based on data and clinical judgment, it cannot be determined at the time of admission whether a condition is present. That is, the case will be paid as though the secondary diagnosis were not present. However, the statute also requires the Secretary to continue counting the condition as a secondary diagnosis that results in a higher IPPS payment when doing the budget neutrality calculations for MS–DRG reclassifications and recalibration. Therefore, we will perform our budget neutrality calculations as though the payment provision did not apply, but Medicare will make a lower payment to the hospital for the specific case that includes the secondary diagnosis. Thus, the provision results in cost savings to the Medicare program.

We note that the provision will only apply when one or more of the selected conditions are the only secondary diagnosis or diagnoses present on the claim that will lead to higher payment. Medicare beneficiaries will generally have multiple secondary diagnoses during a hospital stay, such that beneficiaries having one MCC or CC will frequently have additional conditions that also will generate higher payment. Only a small percentage of the cases will have only one secondary diagnosis that would lead to a higher payment. Therefore, if at least one nonselected secondary diagnosis that leads to higher payment is on the claim, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case. In addition, as discussed in section II.F.3.e. of the preamble of this proposed rule, it is possible to have two severity levels where the HAC does not affect the MS–DRG assignment or for an MS–DRG not to have severity levels. In either of these circumstances, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case.

In section II.F. of the preamble of this proposed rule, we discuss our proposal to add an additional HAC for FY 2012: Contrast-Induced Acute Kidney Injury. In that discussion, we stated that, in FY 2009, there were 38,324 inpatient discharges coded as acute renal failure using ICD–9–CM diagnosis code 584.9 and reported as not present on admission (POA status = N) when reported with one of the above procedure codes submitted through Medicare claims. These cases had an average charge of $29,122 for the entire hospital stay. Further analysis of the FY 2009 claims showed that the average charge was approximately $9,122 more than the average charge for inpatient discharges coded as acute renal failure using ICD–9–CM diagnosis code 584.9 and reported as present on admission (POA status = Y).

The HAC payment provision went into effect on October 1, 2008. Our savings estimates for the next 5 fiscal years are shown below:

Year	Savings (in millions)
FY 2012	$23
FY 2013	$24
FY 2014	$26
FY 2015	$28
FY 2016	$30

B. Effects of Proposed Policy Relating to New Medical Service and Technology Add-On Payments

In section II.I. of the preamble to this proposed rule, we discuss the three applications for add-on payments for new medical services and technologies for FY 2012, as well as the status of the new technology that was approved to receive new technology add-on payments in FY 2011. As explained in that section, add-on payments for new technology under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.I.4. of the preamble of this proposed rule, we have yet to determine whether any of the three applications we received for consideration for new technology add-on payments for FY 2012 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of any potential new technology add-on payments for FY 2012. We note that if any of the three applications are found to be eligible for new technology add-on payments for FY 2012 in

the FY 2012 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2012 in that final rule.

However, because we are proposing to continue to make new technology add-on payments in FY 2012 for the AutoLITT™ (because the technology is still within the 3-year anniversary of the product's entry onto the market), we are providing an estimate of total payments for this technology for FY 2012. We note that new technology add-on payments per case are limited to the lesser of (1) 50 percent of the costs of the new technology or (2) 50 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case. Because it is difficult to predict the actual new technology add-on payment for each case, our estimate below is based on the increase in add-on payments for FY 2012 as if every claim that would qualify for a new technology add-on payments would receive the maximum add-on payment. Therefore, we currently estimate that payments for the AutoLITT™ will increase overall FY 2012 payments by $900,000. For FY 2011, the applicant estimates that approximately 170 Medicare beneficiaries would be eligible for the AutoLITT™. Therefore, based on the applicant's estimate from FY 2011, we currently estimate that payments for the AutoLITT™ will increase overall FY 2012 payments by $900,000.

C. Effects of Proposed Requirements for Hospital Inpatient Quality Reporting (IQR) Program

In section VII.C. of Appendix A of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50662 through 50663), we discussed the impact of the FY 2011 through FY 2014 Hospital Inpatient Quality Reporting (IQR) Program requirements we adopted in that final rule. We estimated that 95 hospitals would not receive the full payment update in any fiscal year from FY 2012 through FY 2014. At the time that analysis was prepared, 104 hospitals did not receive the full payment update in FY 2010.

In section IV.A. of the preamble of this proposed rule, we discuss our proposed requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full update to the standardized amount for FY 2012 through FY 2015. We now estimate that approximately 104 hospitals may not receive the full update in any fiscal year. (In this proposed rule, we are proposing to retire eight of the FY 2011 measures for the FY 2014 payment determination. We believe that this proposal would not have a significant effect on our estimate.) We believe that most of these hospitals would be either small rural or small urban hospitals. However, at this time, information is not available to determine the precise number of hospitals that will not meet the requirements to receive the full annual percentage increase for FY 2012 through FY 2015.

In section IV.A.7. of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225 through 50229), we established Hospital IQR validation requirements for the FY 2012 and FY 2013 payment determinations. Beginning with the FY 2012 payment update, hospitals must pass our validation requirement of a minimum of 75 percent reliability, based upon our chart-audit validation process, for four quarters of data from the last quarter of CY 2011 through the third quarter of CY 2012.

In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45 days from the date of the request to submit the requested records. In section IV.A.6.a. of the preamble of this proposed rule and in proposed § 412.140(d)(1), beginning with the FY 2012 we are proposing to reduce the deadline from 45 days to 30 days for hospitals to return requested medical record documentation to support our validation requirement. This may be an additional administrative burden to hospitals selected for validation. However, this deadline is in line with our QIO regulations at § 476.78 and the total burden would be 18 charts for each for the four quarters that must be copied and mailed in a 30-day period for FY 2012 and subsequent years.

In addition, we are proposing to add a new § 478.78(b)(2)(2) that will require the submission of medical information within 21 days in those situations in which a "serious reportable event" or other circumstance has been identified during the course of a QIO review. We do not believe this will cause a significantly higher administrative burden on the hospitals, since CMS reimburses providers returning medical records to QIOs at the rate of 12 cents per page for copying and approximately $4.00 per chart for postage. Given that we reimburse for the data collection effort, we believe that this proposed requirement represents a minimal burden to providers. We have continued our efforts to ensure that QIOs provide assistance to all hospitals that wish to participate in the Hospital IQR Program.

In section IV.A.6.b. of the preamble of this proposed rule, for FY 2014 payment determinations and subsequent years, we are proposing to add two strata to the current Hospital IQR validation sample of SCIP, AMI, HF, and PN cases. For the first stratum, we are proposing to select three cases per selected hospital per quarter to validate the CLABSI measure using a two step selection process that would target potential patients with positive infection from blood culture results and a Central Venous Catheter. The requirement of an additional 3 charts per hospital submitted for validation for the CLABSI measure would result in approximately 2,400 total additional charts per quarter being submitted to CMS by all selected hospitals. We reimburse hospitals for the cost of sending charts to the CDAC contractor at the rate of 12 cents per page for copying and approximately $4.00 per chart for postage. Our experience shows that the average chart received by the CDAC contractor is approximately 275 pages. Thus, we would expend approximately $88,800 per quarter to collect the additional charts we need to validate the CLASBI measure. Additionally, we will collect the CLABSI-specific data elements from all charts currently requested for Hospital IQR validation. We would validate a total of 15 records per quarter per validated hospital in 5 strata (SCIP, AMI, HF, PN, CLABSI and the proposed ED/Global Immunization measure).

In section IV.A.6.b. of the preamble of this proposed rule, for FY 2014 and subsequent years, we are proposing to add a second stratum to our validation sample, which would enable us to validate the EDT and the Immunization for Influenza and Immunization for Pneumonia global measures. Thus, we would be validating a total of 18 records per quarter per selected hospital in 6 strata ((1) SCIP, (2) AMI, (3) HF, (4) PN, (5) CLABSI, and (6) EDT/immunization measures). Under the assumptions outlined above, we would expend approximately $88,800 per quarter to collect the additional charts for the EDT/immunization measures. The proposed total requirement of 18 charts per hospital (should we adopt both the proposed CLABSI validation requirement and the proposed EDT/immunization validation requirement) would result in approximately 14,400 charts per quarter being submitted to CMS. Using the assumptions discussed above, for the FY 2014 Hospital IQR Program, we estimate that CMS would have expenditures of approximately $532,800 per quarter related to the validation requirement. Additionally, we will collect the CLABSI-specific data and the EDT/Immunization data elements from all charts currently requested for Hospital IQR validation. We would validate a total of 18 records per quarter per validated hospital in 6 strata (SCIP, AMI, HF, PN, CLABSI and the proposed ED/Global Immunization measure). We do not believe this will be an additional burden on the hospitals since this data will be abstracted from records already submitted.

Given that we reimburse for the data collection effort, we believe that a requirement for 18 charts per hospital per quarter represents a minimal burden to participating hospitals selected for validation.

Finally, with respect to our proposed validation requirements, we also are proposing for FY 2015 to select additional hospitals for validation if they were open under their current CCNs in FY 2012 but not selected for validation in the three previous annual Hospital IQR Program validation selections. This proposal could affect data collection costs and burdens, but we are unable to estimate any impact at this time.

We are proposing to adjust the Hospital IQR Program data submission deadline from 4½ months to 104 days. While the proposed shortened time frame may create a new administrative burden for hospitals, we believe that this burden is reduced because many hospitals currently report AMI, HF, SCIP, and PN data to the Joint Commission within 4 months following a discharge quarter. We believe that our proposed 104 day deadline is relatively consistent with other industry submission deadlines.

D. Effects of Additional Proposed Hospital Value-Based Purchasing (VBP) Program Requirements

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through

a reduction to the FY 2013 base operating MS–DRG payment for each discharge of 1 percent, as required by section 1886(o)(7)(B)(i) of the Act. The applicable percentage for FY 2014 is 1.25 percent, for FY 2015 is 1.5 percent, for FY 2016 is 1.75 percent, and for FY 2017 and subsequent years is 2 percent.

In section IV.B. of the preamble of this proposed rule, we are proposing additional requirements for the FY 2014 Hospital VBP Program. Specifically, we are proposing the addition of a Medicare Spending per Beneficiary Measure, how the proposed measure would be scored, and the measure's proposed performance period and proposed baseline period. Because this additional measure is claims-based and is required for the Hospital IQR Program, its inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

E. Effects of Proposed Requirements for Hospital Readmissions Reduction Program

In section IV.C. of the preamble of this proposed rule, we are proposing the selection of three high cost, high volume conditions for the Hospital Readmission Reduction Program FY 2013 payment reduction, and the definition of readmission for these conditions. We also are proposing the use of the following three measures for these conditions for the FY 2013 payment determination:

- Heart failure [HF] 30-day Risk Standardized Readmission Measure
- Acute Myocardial Infarction [AMI] 30-day Risk Standardized Readmission Measure
- Pneumonia [PN] 30-day Risk Standardized Readmission Measure

These three risk-adjusted NQF endorsed measures will be calculated by CMS for hospitals subject to this provision using Medicare FFS Part A and B claims data, and require no submission of additional data by the hospital. Therefore, there is no data collection burden associated with this provision for FY 2013. These measures also are used under the Hospital IQR Program, and have been publicly reported on the *Hospital Compare* Web site since 2009. Therefore, there is a high degree of familiarity and acceptance among the stakeholder community with regard to these measures.

We also are proposing a methodology for calculating the Excess Readmission Ratio using these three measures for the FY 2013 payment determination. This would be defined as a ratio of the number of risk-adjusted readmissions (based on actual readmissions) for the given condition at a specified hospital compared with the number of readmissions that would be expected for an average hospital caring for the same patients. Below is a description of this calculation:

Numerator—Adjusted number of readmissions at specific hospital (calculated for each patient and add up results for all patients):

Hospital-specific readmission effect + average hospital contribution to readmission risk + [risk factor weights × patient risk factors]

Denominator—Number of readmissions if an average hospital treated the same patients (calculated for each patient and summed for all patients):

Average hospital contribution to readmission risk + [risk factor weights × patient risk factors]

We are proposing a minimum case threshold of 25 cases for a given condition in order to have an Excess Readmission Ratio calculated. Using the proposed 25 case threshold, we have analyzed the distribution of Excess Readmission Ratio calculations on various types of IPPS hospitals. The results of these analyses are shown in the three tables below.

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Distribution of Excess Readmission Ratio for Acute Myocardial Infarction (AMI): AMI Readmission Distribution of Excess Readmission Ratio (for hospitals with greater than 25 AMI cases between July 2006-June 2009)

Hospital Characteristic	Hospitals with (≥ 25 cases over 3-year period)	Hospitals with Excess Readmission Ratio ≤ 1*	Percentage of Hospitals with Excess Readmission Ratio ≤ 1*	Percentile								
				Mean	5th	10th	25th	50th	75th	90th	95th	Hospitals with < 25 cases (not included in distribution)
OVERALL	2,477	1,248	50.4	1.0019	0.8953	0.9238	0.9627	0.9997	1.0412	1.0795	1.1065	1,999
Region**												
New England	148	72	48.6	1.0060	0.9172	0.9331	0.9623	1.0049	1.0400	1.0949	1.1104	30
Mid Atlantic	338	106	31.4	1.0325	0.9266	0.9544	0.9894	1.0292	1.0690	1.1137	1.1546	61
South Atlantic	448	235	52.5	0.9977	0.8918	0.9207	0.9608	0.9951	1.0370	1.0717	1.0938	203
East North Central	408	210	51.5	1.0046	0.9022	0.9260	0.9649	0.9991	1.0435	1.0884	1.1154	268
East South Central	171	69	40.4	1.0143	0.9338	0.9467	0.9747	1.0084	1.0518	1.0803	1.0967	209
West North Central	166	92	55.4	0.9930	0.8839	0.9190	0.9502	0.9928	1.0311	1.0710	1.0922	428
West South Central	288	149	51.7	0.9964	0.8928	0.9225	0.9612	0.9952	1.0352	1.0632	1.0799	300
Mountain	131	94	71.8	0.9726	0.8758	0.8913	0.9328	0.9744	1.0067	1.0511	1.0717	188
Pacific	275	172	62.5	0.9797	0.8707	0.8979	0.9355	0.9839	1.0229	1.0591	1.0750	191
Associated Areas	25	9	36.0	1.0306	0.9610	0.9649	0.9846	1.0276	1.0632	1.1039	1.1364	21
Bed Size**												
1 to 99 beds	395	220	55.7	0.9987	0.9279	0.9451	0.9710	0.9953	1.0275	1.0516	1.0717	1,556
100 to 199 beds	731	358	49.0	1.0015	0.9096	0.9345	0.9646	1.0019	1.0375	1.0713	1.0926	274
200 to 299 beds	517	272	52.6	0.9979	0.8868	0.9137	0.9541	0.9961	1.0423	1.0771	1.1059	41
300 to 399 beds	320	164	51.3	0.9994	0.8686	0.9036	0.9507	0.9989	1.0511	1.0923	1.1145	19
400 to 499 beds	170	78	45.9	1.0116	0.8816	0.9021	0.9610	1.0067	1.0636	1.1090	1.1391	7
500+ beds	265	116	43.8	1.0125	0.8839	0.9007	0.9643	1.0115	1.0632	1.1139	1.1516	2
Teaching Status**												
Teaching	896	439	49.0	1.0061	0.8840	0.9121	0.9580	1.0028	1.0530	1.0992	1.1293	175
Non-Teaching	1,502	769	51.2	0.9994	0.9058	0.9284	0.9649	0.9987	1.0353	1.0672	1.0914	1,724
Urban/Rural Status**												
Urban	2,279	1,146	50.3	1.0017	0.8928	0.9211	0.9615	0.9998	1.0418	1.0797	1.1072	972
Rural	119	62	52.1	1.0061	0.9409	0.9517	0.9713	0.9966	1.0328	1.0761	1.0887	927

* With ≥ 25 cases over 3-year period.

** Total number of hospitals with available hospital characteristics and with > 25 cases over 3-year period equals 2,398.

Distribution of Excess Readmission Ratio for Heart Failure (HF):
Heart Failure Readmission Distribution of Excess Readmission Ratio
(for hospitals with greater than 25 HF cases between July 2006-June 2009)

Hospital Characteristic	Hospitals with (≥ 25 cases over 3-year period)	Hospitals with Excess Readmission Ratio ≤ 1*	Percentage of Hospitals with Excess Readmission Ratio ≤ 1*	Percentile								
				Mean	5th	10th	25th	50th	75th	90th	95th	Hospitals with < 25 cases (not included in distribution)
OVERALL	4,209	2,171	51.6	1.0021	0.8799	0.9108	0.9527	0.9971	1.0484	1.0991	1.1362	550
Region**												
New England	174	99	56.9	0.9933	0.8830	0.9058	0.9418	0.9879	1.0382	1.0940	1.1121	5
Mid Atlantic	397	135	34.0	1.0376	0.9020	0.9314	0.9788	1.0354	1.0936	1.1485	1.1788	6
South Atlantic	639	323	50.5	1.0021	0.8860	0.9097	0.9517	0.9993	1.0507	1.0962	1.1304	26
East North Central	672	378	56.3	0.9933	0.8740	0.8983	0.9413	0.9890	1.0423	1.0937	1.1302	20
East South Central	381	156	40.9	1.0225	0.9059	0.9291	0.9646	1.0142	1.0708	1.1313	1.1708	14
West North Central	519	304	58.6	0.9918	0.8876	0.9174	0.9482	0.9867	1.0267	1.0730	1.1143	136
West South Central	560	256	45.7	1.0112	0.8920	0.9212	0.9650	1.0082	1.0549	1.1052	1.1373	81
Mountain	271	188	69.4	0.9664	0.8511	0.8789	0.9315	0.9706	1.0118	1.0435	1.0628	93
Pacific	418	247	59.1	0.9892	0.8671	0.9035	0.9458	0.9841	1.0392	1.0823	1.1111	83
Associated Areas	34	12	35.3	1.0304	0.9365	0.9515	0.9877	1.0253	1.0665	1.1122	1.1461	14
Bed Size**												
1 to 99 beds	1,755	947	54.0	0.9999	0.8980	0.9206	0.9556	0.9939	1.0394	1.0865	1.1190	414
100 to 199 beds	983	467	47.5	1.0080	0.8833	0.9145	0.9584	1.0042	1.0517	1.1119	1.1427	38
200 to 299 beds	547	284	51.9	1.0019	0.8647	0.8959	0.9476	0.9966	1.0565	1.1125	1.1485	15
300 to 399 beds	337	176	52.2	1.0003	0.8626	0.8939	0.9449	0.9964	1.0586	1.1052	1.1314	4
400 to 499 beds	176	93	52.8	0.9979	0.8501	0.8857	0.9290	0.9920	1.0596	1.1275	1.1578	3
500+ beds	267	131	49.1	1.0004	0.8506	0.8908	0.9397	1.0017	1.0549	1.1051	1.1577	4
Teaching Status**												
Teaching	1,036	547	52.8	1.0005	0.8681	0.9001	0.9454	0.9937	1.0534	1.1085	1.1476	49
Non-Teaching	3,029	1,551	51.2	1.0027	0.8838	0.9149	0.9554	0.9980	1.0469	1.0978	1.1328	429
Urban/Rural Status**												
Urban	3,160	1,666	52.7	0.9996	0.8742	0.9048	0.9487	0.9941	1.0476	1.1005	1.1366	205
Rural	905	432	47.7	1.0110	0.9126	0.9312	0.9631	1.0043	1.0517	1.0984	1.1378	273

* With ≥ 25 cases over 3-year period.

** Total number of hospitals with available hospital characteristics and with > 25 cases over 3-year period equals 4,065.

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Distribution of Excess Readmission Ratio for Pneumonia (PN):
Pneumonia Readmission Distribution of Excess Readmission Ratio
(for hospitals with greater than 25 Pneumonia cases between July 2006-June 2009)

Hospital Characteristic	Hospitals with (≥ 25 cases over 3-year period)	Hospitals with Excess Readmission Ratio ≤ 1*	Percentage of Hospitals with Excess Readmission Ratio ≤ 1*	Percentile								
				Mean	5th	10th	25th	50th	75th	90th	95th	Hospitals with < 25 cases (not included in distribution)
OVERALL	4,450	2,351	52.8	1.0021	0.8763	0.9019	0.9435	0.9944	1.0531	1.1134	1.1538	363
Region**												
New England	178	88	49.4	1.0086	0.8750	0.9045	0.9488	1.0011	1.0603	1.1262	1.1605	3
Mid Atlantic	399	143	35.8	1.0458	0.9021	0.9360	0.9735	1.0326	1.1033	1.1773	1.2288	5
South Atlantic	653	301	46.1	1.0135	0.8858	0.9187	0.9586	1.0073	1.0639	1.1207	1.1494	16
East North Central	679	368	54.2	1.0003	0.8614	0.8907	0.9340	0.9889	1.0557	1.1231	1.1645	12
East South Central	381	132	34.6	1.0381	0.9032	0.9248	0.9719	1.0329	1.0938	1.1544	1.2052	17
West North Central	618	379	61.3	0.9831	0.8766	0.9027	0.9365	0.9785	1.0207	1.0741	1.1052	42
West South Central	590	343	58.1	0.9917	0.8682	0.8928	0.9344	0.9871	1.0399	1.0922	1.1427	59
Mountain	323	236	73.1	0.9605	0.8487	0.8812	0.9187	0.9615	1.0027	1.0525	1.0748	47
Pacific	443	273	61.6	0.9822	0.8590	0.8865	0.9369	0.9827	1.0258	1.0774	1.1090	65
Associated Areas	36	11	30.6	1.0395	0.9343	0.9575	0.9820	1.0382	1.0819	1.1441	1.1605	13
Bed Size**												
1 to 99 beds	1,982	1,187	59.9	0.9910	0.8784	0.9019	0.9386	0.9812	1.0348	1.0914	1.1327	214
100 to 199 beds	989	501	50.7	1.0067	0.8771	0.9044	0.9466	0.9989	1.0616	1.1199	1.1555	36
200 to 299 beds	547	261	47.7	1.0081	0.8684	0.8920	0.9450	1.0028	1.0609	1.1270	1.1670	18
300 to 399 beds	37	142	42.1	1.0139	0.8567	0.8933	0.9551	1.0154	1.0710	1.1370	1.1708	4
400 to 499 beds	177	80	45.2	1.0167	0.8763	0.9194	0.9488	1.0105	1.0646	1.1383	1.2018	3
500+ beds	268	103	38.4	1.0296	0.8579	0.9105	0.9583	1.0215	1.0819	1.1573	1.2268	4
Teaching Status**												
Teaching	1,049	470	44.8	1.0144	0.8614	0.8997	0.9492	1.0108	1.0682	1.1383	1.1971	46
Non-Teaching	3,251	1,804	55.5	0.9981	0.8786	0.9015	0.9418	0.9892	1.0476	1.1072	1.1428	233
Urban/Rural Status**												
Urban	3,215	1,651	51.4	1.0032	0.8671	0.8953	0.9421	0.9976	1.0565	1.1182	1.1595	179
Rural	1,085	623	57.4	0/9985	0.8924	0.9120	0.9460	0.9871	1.0405	1.1027	1.1416	100

* With ≥ 25 cases over 3-year period.

** Total number of hospitals with available hospital characteristics and with ≥ 25 cases over 3-year period equals 4,300.

The three tables above show the distribution of Excess Readmission Ratios for AMI hospitalizations, HF hospitalizations, and PN hospitalizations respectively. The data for these tables come from the publicly-reported risk-standardized rates of readmission reported in 2010 on *Hospital Compare* (representing hospitalizations between July 2006 and June 2009). The distributions of the ratios are shown only for hospitals with at least 25 cases included in the measures over the 3-year period.

The first column of the tables lists hospital characteristics (census region, bed size, teaching status, and urban/rural location) and the second column shows the number of hospitals included in the distribution for the particular category. For example, for the first table, AMI readmission, a total of 2,477 hospitals had at least 25 included hospitalizations between July 2006 and June 2009. Of these hospitals, 148 were in the New England region.

The third and fourth columns show the number and percentage of hospitals (of those with 25 or more cases) in the particular category with an Excess Readmission Ratio less than or equal to 1; such hospitals would not have their payments adjusted due to the Readmission Reduction Program because they would not be found to have "excess" readmissions. For example in the first table, for AMI readmissions, 72 of the 148 hospitals in the New England region (that had 25 or more AMI hospitalizations) had an Excess Readmission Ratio of less than or equal to 1, which means that 48.6 percent of the hospitals in the New England region (with at least 25 cases of AMI in 3 years) would not have their payments affected by the Hospital Readmission Reduction Program, whereas the remaining hospitals would be at risk of a payment reduction based on excess readmissions.

The following eight columns show the distribution of the excess readmissions. For example, for AMI, in the New England region the mean Excess Readmission Ratio is 1.0060, the lowest 5th percentile hospitals had ratios of 0.9172 or less and the highest 95th percentile of hospitals had Excess Readmission Ratios of 1.1104 or greater.

The final column of each table shows the number of hospitals, within the given category, that are not included in the distribution based on sample size. For example, for AMI, in the New England region 30 hospitals are not included in the distribution because they had fewer than 25 AMI hospitalizations over the 3-year period. Currently, 25 hospitalizations is the minimum number of hospitalizations for public reporting. Hospitals with fewer than 25 cases for a given condition do not have risk-standardized rates of readmission reported on *Hospital Compare.* We are proposing to use this threshold for inclusion in the Readmission Reduction Program.

Overall these analyses show, for all three conditions, that in all hospital categories approximately half of the hospitals are at risk of payment reductions based on excess readmissions. This percentage does not vary greatly by region; however for all three measures the Mid-Atlantic region has the lowest percentage of hospitals with Excess Readmission Ratios of less than or equal to 1 and, therefore, the Mid-Atlantic region is the region with the highest percentage of hospitals at risk of payment reduction. By contrast, the Mountain region has the largest percentage of hospitals with ratios of less than or equal to 1. The distributions do not differ greatly by bed size, though the largest hospitals have slightly lower percentages of hospitals with ratios less than or equal to 1 for AMI and PN. The distributions do not vary greatly by teaching status or rural/urban location for any of the measures.

We also are proposing to publicly report the readmission rates for these three measures on the *Hospital Compare* Web site using the current processes employed for public reporting of these measures, which includes a preview period. We believe that this also poses no additional burden to hospitals, as they currently employ this system for Hospital IQR public reporting.

F. Effects of Proposed Policy Changes Relating to Payment Adjustments for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME)

In section IV.G. of the preamble of this proposed rule, we proposed to exclude from the hospital's disproportionate patient percentage (DPP) of the Medicare DSH calculation and from the available bed day count used to calculate the DSH payment adjustment and the IME payment adjustments, patient days for hospice patients receiving inpatient hospice services in a hospital setting. For the purpose of the DSH payment calculation, the patient days for hospice patients receiving inpatient hospice services in the hospital would be excluded from both the numerator and the denominator of the Medicare and Medicaid fractions. As such, the impact on hospitals' DSH payment adjustment would vary based on the demographic composition of an individual hospital's patient population. In other words, under this proposal, some hospitals may receive increased DSH payment adjustments and other hospitals may expect to receive lower DSH payment adjustments, depending on the extent to which a hospital provides inpatient hospice services to hospice patients.

The proposed change in policy to exclude from the available bed count, patient days for hospice patients receiving hospice services in an inpatient hospital setting only impacts DSH payments for limited situations. Specifically, urban hospitals with fewer than 100 beds or rural hospitals with fewer than 500 beds, with the exception of rural referral centers or MDHs, are subject to a cap of their DSH payment adjustment of 12 percent. Thus, a decrease in the number of available beds due to the exclusion of beds used to provide inpatient hospice services only impacts a provider's DSH payments if it results in the hospital's bed count falling below the bed count threshold. Should a hospital fall below the bed count threshold, it would become subject to the Medicare DSH payment adjustment cap and its DSH payment could decrease.

For IME payment purposes, a decrease in a hospital's number of available beds results in an increase in the resident-to-bed ratio. The exclusion of bed days associated with hospice patients from the available bed count for IME would reduce the available beds, increase the resident-to-bed ratio, and, consequently, may increase IME payments to teaching hospitals depending on the extent to which these hospitals were providing inpatient hospice services to hospice patients.

G. Effects of the FY 2012 Low-Volume Hospital Payment Adjustment

As discussed in section IV.E. of the preamble to this proposed rule, we discuss the provisions of sections 3125 and 10314 of the Affordable Care Act that expand eligibility for the low-volume hospital payment adjustment at section 1886(d)(12) of the Act for FYs 2011 and 2012 to hospitals with less than 1,600 Medicare discharges (instead of the prior requirement of less than 800 total, Medicare and non-Medicare, discharges) and hospitals that are located more than 15 miles from other IPPS hospitals (rather than the prior requirement of more than 25 miles). The payment adjustment is also changed from an empirically determined additional 25 percent payment adjustment to qualifying hospitals with less than 200 total discharges (69 FR 49099 through 49102 and 70 FR 47432 through 47434) to a continuous, linear sliding scale adjustment ranging from an additional 25 percent payment adjustment to qualifying hospitals with 200 or fewer Medicare discharges to no additional payment to hospitals with 1,600 or more Medicare discharges (75 FR 50241).

Based on FY 2010 claims data (December 2010 update of the MedPAR file), we estimate that 492 out of the 502 hospitals in our database that qualified as a low-volume hospital for FY 2011 would continue to meet the Medicare discharges criterion to qualify as a low-volume hospital for FY 2012. For purposes of this impact analysis, we are assuming that all of these 492 hospitals would continue to meet the distance criterion in FY 2012. If all 492 hospitals qualified for the low-volume payment adjustment in FY 2012, we estimate that these hospitals would receive an additional estimated $280 million based on the proposed FY 2012 low-volume payment adjustment (described in section IV.E. of the preamble of this proposed rule) as compared to FY 2012 payments without the proposed low-volume adjustment. (As discussed in section IV.E. of the preamble of this proposed rule, for FY 2012, we are proposing to determine a hospital's number of Medicare discharges based on the most recent update of the FY 2010 MedPAR files (that is, the December 2010 update for this proposed rule.)

In addition, we identified an additional 89 hospitals in our database that would meet the Medicare discharges criterion to qualify as a low-volume hospital for FY 2012 based on our proposal set forth in section IV.E. of the preamble of this proposed rule. (We note that these 89 hospitals did not meet the discharge criterion to qualify as a low-volume hospital for FY 2011.) However, we are not able to estimate the number of these 89 hospitals that would also meet the distance criterion. The actual number of hospitals that would also meet the distance criterion to qualify as

a low-volume hospital would very likely be significantly less than the estimated 89 maximum number of potential additional low-volume hospitals for FY 2012 (as compared to FY 2011). (We note that approximately 40 percent of the hospitals that met the discharge criterion for FY 2011 also met the mileage criterion and, therefore, are eligible to receive the low-volume payment adjustment in FY 2011.) If all these 89 hospitals were to qualify as low-volume hospitals in FY 2012, we estimate that an additional $26 million in payments would be made for the FY 2012 low-volume payment adjustment at section 1886(d)(12) of the Act.

H. Effects of Proposed Changes Relating to MDHs

As discussed in section IV.H. of the preamble to this proposed rule, section 3124 of Public Law 111–148 extended the MDH program for 1 additional year, from the end of FY 2011 (that is, for discharges before October 1, 2011) to the end of FY 2012 (that is, for discharges before October 1, 2012). The extension had no impact on FY 2011. For FY 2012, the extension allows the continuation of MDH status and the payment methodology, for an MDH to be paid its hospital-specific rate, based on its FY 1982, 1987, or 2002 updated costs per discharge, rather than the Federal rate, if this results in a greater aggregate payment. Therefore, the impact of the extension is one additional year of hospital-specific rate payments, when greater than Federal rate payments, for these hospitals as MDHs, rather than Federal rate payments for these hospitals without special treatment as MDHs.

I. Effects of Proposed Policy Relating to CRNA Services Furnished in Rural Hospitals and CAHs

In section IV.I. of this preamble of this proposed rule, we discuss the interim final rule with comment that appeared in the November 24, 2010 **Federal Register** (75 FR 72256) regarding pass-through payment for CRNA services. In that interim final rule with comment period, we stated that we were changing the effective date of our policy to allow hospitals and CAHs that have reclassified as rural under 42 CFR 412.103 to be eligible for CRNA pass-through from "cost reporting periods beginning on or after October 1, 2010" to "December 2, 2010." In section IV.I. of the preamble of this proposed rule, we state that we intend to respond to comments received on the interim final rule with comment period in the FY 2012 IPPS/LTCH PPS final rule. Also in the interim final rule with comment (75 FR 72258), we stated that a change to the effective date would only affect at most a small subset of hospitals and CAHs affected by the change to the regulations adopted in the FY 2010 IPPS/LTCH PPS final rule and, for this reason, we expected the change to the effective date in the interim final rule with comment period to have a minor impact on Federal expenditures.

J. Effects of Proposed Changes Relating to ESRD Add-On Payment

In section IV.L. of the preamble of this proposed rule, we discuss our proposal to clarify that the term "Medicare discharges" as used in § 412.104(a) refers to discharges of all beneficiaries entitled to Medicare Part A; that is, discharges associated with individuals entitled to Part A, including discharges of individuals receiving benefits under original Medicare, discharges of individuals whose inpatient benefits are exhausted or whose stay was not covered by Medicare, and discharges for individuals enrolled in Medicare Advantage Plans, cost contracts under section 1876 of the Act (health maintenance organizations (HMOs)) and competitive medical plans (CMPs).

We are not able to provide a detailed analysis of the impact of the clarification of this definition. We are not proposing any changes to the existing regulations at § 412.104 under which we will continue to provide an additional Medicare payment to a hospital for inpatient services provided to Medicare beneficiaries with ESRD who receive a dialysis treatment during a hospital stay, if the hospital has established that ESRD Medicare beneficiary discharges, excluding certain MS–DRGs for renal failure, admission for renal dialysis, and kidney transplant, where the beneficiary received dialysis services during the inpatient stay, are 10 percent or more of its total Medicare discharges. We note that this clarification could change both the denominator (total Medicare discharges) and the numerator (ESRD Medicare beneficiary discharges, excluding certain MS–DRGs for renal failure, admission for renal dialysis, and kidney transplant) associated with this calculation. As a result of our proposed clarification, these discharges would be included in the denominator of the calculation for the determination of eligibility for the ESRD additional payment to hospitals. Similarly, for the numerator of this calculation, we also would include all discharges of ESRD beneficiaries who are entitled to Medicare Part A and who receive inpatient dialysis, subject to the exclusions of certain MS–DRG codes described above. Depending on whether or not the additional discharges are for ESRD beneficiaries, the calculation may increase or decrease.

K. Effects of Proposed Changes Relating to the Reporting Requirements for Pension Costs for Medicare Cost-Finding and Wage Reporting Purposes

In sections III.D.3. and IV.M. of the preamble of this proposed rule, we are proposing to revise our policy for determining pension cost for Medicare purposes. We are setting forth two distinct proposals: One proposal for determining and reporting defined benefit pension costs on the cost report for Medicare cost finding purposes and the other for determining and reporting defined benefit pension costs for Medicare wage index purposes. The allowable pension cost under the current rules and the proposed policies are based on the amount funded. The current rules impose an actuarially based limit on the allowable amount and the proposed rules limit the costs based on historical funding data. Because the current rules and the proposed policies are both tied to the amount funded, we expect that there would be minimal impact. We note that it is not possible to determine a precise impact for Medicare cost-finding purposes because we do not currently have data in the form and manner required to calculate the pension costs for all providers under our proposal. Moreover, because we lack these data, we are unable to determine a hospital-level impact for the Medicare wage index. We note that our proposal may result in redistribution within the Medicare wage index, but section 1886(d)(3)(E) of the Act requires any adjustments or updates made to the Medicare wage index to be budget neutral.

L. Effects of Implementation of Rural Community Hospital Demonstration Program

In section IV.N. of the preamble of this proposed rule, we discuss our implementation of section 410A of Public Law 108–173, as amended, which, prior to the amendments made by the Affordable Care Act, required the Secretary to establish a demonstration that would modify reimbursement for inpatient services for up to 15 small rural hospitals. Section 410A(c)(2) requires that "[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented." As discussed in section IV.N. of the preamble of this proposed rule, in the IPPS final rules for each of the previous 7 fiscal years, we have estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we are proposing to adjust the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are proposing to apply budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration. We believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that "aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration * * * was not implemented" but does not identify the range across which aggregate payments must be held equal.

An extension of this demonstration was mandated by the Affordable Care Act. The demonstration is extended for an additional 5 years and expanded to include up to a total of 30 hospitals. We are proposing to make an adjustment in the FY 2012 IPPS final rule of $52,642,213 to the national IPPS rates. This amount accounts for an estimate of the demonstration cost for FY 2012 for the 8 hospitals that are currently participating in the demonstration and, in addition, an estimate of the cost of participation in the demonstration for the 19 additional hospitals selected to participate as a result of the expansion of the demonstration under the Affordable Care Act. In addition, for this FY 2012 proposed rule, we are proposing that the budget neutrality adjustment also account for any differences between the cost of the

demonstration program for hospitals participating in the demonstration during FYs 2007 and 2008, represented by their cost reports beginning in FYs 2007 and 2008, and the amount that was offset by the budget neutrality adjustment for FYs 2007 and 2008. The estimated $52,642,213 that we are proposing to offset does not account for any differences between the cost of the demonstration program for hospitals participating in the demonstration during FYs 2007 and 2008 and the amount that was offset by the budget neutrality adjustment for FYs 2007 and 2008 because the specific numeric value associated with this component of the proposed adjustment to the national IPPS rates cannot be known at this time. This is because settled cost reports beginning in FYs 2007 and 2008 of the hospitals participating during FYs 2007 and 2008 in the demonstration are not available yet. We anticipate that those settled cost reports may be available prior to the publication of the FY 2012 IPPS/LTCH PPS final rule. To this extent that they become available prior to publication of the FY 2012 IPPS/LTCH PPS final rule, under our proposal these costs would be included in the amount to be offset by the FY 2012 budget neutrality adjustment.

M. Effects of Proposed Changes to the List of MS–DRGs Subject To Postacute Care Transfer and DRG Special Pay Policy

In section IV.P. of the preamble to this proposed rule, we discuss proposed changes to the list of MS–DRGs subject to the postacute care transfer and DRG special payment policies. As reflected in Table 5 listed in section VI of the Addendum to this proposed rule and available via the Internet, using criteria set forth in regulation at § 412.4, we evaluated MS–DRG charges, discharge, and transfer data to determine which MS–DRGs qualify for the postacute care transfer and DRG special pay policies. We note that we are making no proposal to change these payment policies in this FY 2012 proposed rule. We are proposing to change the status of certain MS–DRGs as a result of proposals to revise the MS–DRGs for FY 2012. We are proposing to change the status of eight MS–DRGs to qualify for the postacute care transfer policy in FY 2012, after not qualifying in FY 2011. An additional five MS–DRGs that qualified under the policy in FY 2011 do not qualify in FY 2012, and we are proposing to change their statuses accordingly. Finally, three MS–DRGs now qualify for the MS–DRG special pay policy in FY 2012 after not qualifying in FY 2011, and we are proposing to add them to the list of qualifying MS–DRGs. Column 4 of Table I in this Appendix A shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The analysis and methods determining the proposed changes due to the MS–DRGs and relative weights accounts for and includes changes in MS–DRG postacute care transfer and special pay policy statuses. We refer readers to section VI.D. of this Appendix for a more detailed discussion of payment impacts due to MS–DRG reclassification policies.

N. Effects of Proposed Changes Relating to Hospital Services Furnished Under Arrangements

In section VI.B. of the preamble of this proposed rule, we are proposing to clarify that only diagnostic and therapeutic services (that is, ancillary services) may be provided outside the hospital under arrangement. Routine services must be provided in the hospital in which the patient is a registered inpatient. We are aware of only a few cases where routine services are being provided outside the hospital other than where the patient is a registered inpatient. Therefore, we have determined that the impact of this clarification is negligible.

O. Effects of Proposed Change Relating to CAH Payment for Ambulance Services

In section VI.C. of the preamble of this proposed rule, we discuss our proposal to revise the regulations at § 413.70(b)(5) to state that, effective for cost reporting periods beginning on or after October 1, 2011, payment for ambulance services furnished by a CAH or by a CAH-owned entity is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. In addition, we are proposing to revise the regulations at § 413.70(b)(5) to state that, effective for cost reporting periods beginning on or after October 1, 2011, if there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH, but there is a CAH-owned and operated entity located more than a 35-mile drive from the CAH, the CAH owned and operated entity would be paid at 101 percent of reasonable cost for its ambulance services as long as that entity is the closest provider or supplier of ambulance services to the CAH. We believe this proposal would continue to allow for sufficient ambulance services to CAHs. We do not have sufficient information or data to determine how many CAH-owned and operated entities would qualify under the proposal. As a result, we are unable to quantify the financial impact of this proposed for payment based on 101 percent of reasonable cost. However, even those entities that do not qualify for payment based on 101 percent of reasonable cost would be paid for ambulance services under the Medicare ambulance fee schedule.

VIII. Effects of Proposed Changes in the Capital IPPS

A. General Considerations

For the impact analysis presented below, we used data from the December 2010 update of the FY 2010 MedPAR file and the December 2010 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2010 update of the most recently available hospital cost report data (FYs 2008 and 2009) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment as described below. In addition, as discussed in section V.E. of the preamble to this proposed rule, we are proposing to make a −1.0 percent documentation and coding adjustment to the national capital rate for FY 2012 in addition to the −0.6 percent adjustment established for FY 2008, the −0.9 percent adjustment for FY 2009, and the −2.9 percent adjustment for FY 2011. This results in a proposed cumulative adjustment factor of 0.9479 that we applied in determining the proposed FY 2012 national capital rate to account for improvements in documentation and coding that do not reflect real changes in case mix under the MS–DRGs. We note that we applied a −2.6 percent documentation and coding adjustment to the Puerto Rico-specific capital rate in FY 2011, which reflects the entire amount of our current estimate of the effects of documentation for FYs 2008 and 2009 that do not reflect real changes in case-mix under the MS–DRGs. Therefore, we are not proposing to adjust the proposed Puerto Rico-specific capital rate in FY 2012 to account for changes in documentation and coding.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each proposed change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2010 update of the FY 2010 MedPAR file, we simulated payments under the capital IPPS for FY 2011 and FY 2012 for a comparison of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (Indian Health Service hospitals and hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating proposed capital IPPS payments in FY 2012 is as follows:

(Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME adjustment factor, if applicable).

In addition to the other proposed adjustments, hospitals may also receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

• We estimate that the Medicare case-mix index would increase by 1.0 percent in both FYs 2011 and 2012.

• We estimate that the Medicare discharges would be approximately 11.8 million in FY 2011 and 12.2 million in FY 2012.

• The capital Federal rate was updated beginning in FY 1996 by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the preamble of this proposed rule, the proposed update is 1.5 percent for FY 2012.

• In addition to the proposed FY 2012 update factor, the proposed FY 2012 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality factor of 1.0005, and a proposed outlier adjustment factor of 0.9406. As discussed in section III.A.4. of the Addendum to this proposed rule, an exceptions adjustment factor is not necessary in FY 2012 because there are no longer any hospitals eligible to receive special exceptions payments in FY 2012. However, the special exceptions adjustment factor was not built permanently into the capital rate; that is, was not applied cumulatively. Therefore, because there will be no special exceptions payments in FY 2012, we are only applying an adjustment to restore the special exceptions adjustment that was applied to the FY 2011 capital rate, that is, 1.0004 (calculated as 1/0.9996).

• For FY 2012, as discussed above and in section V.E. of the preamble to this proposed rule, we are proposing to apply a cumulative 0.9479 adjustment in determining the proposed FY 2012 national capital rate for changes in documentation and coding that are expected to increase case-mix under the MS–DRGs but do not reflect real case-mix change. This cumulative adjustment of 0.9479 reflects the proposed additional −1.0 percent adjustment in FY 2012 for the effects of documentation and coding in FYs 2008 and 2009.

B. Results

We used the actuarial model described above to estimate the potential impact of our proposed changes for FY 2012 on total capital payments per case, using a universe of 3,419 hospitals. As described above, the individual hospital payment parameters are taken from the best available data, including the December 2010 update of the FY 2010 MedPAR file, the December 2010 update to the PSF, and the most recent cost report data from the December 2010 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2011 and estimated total payments per case proposed for FY 2012 based on the proposed FY 2012 payment policies. Column 2 shows estimates of payments per case under our model for FY 2011. Column 3 shows estimates of payments per case under our model for FY 2012. Column 4 shows the total percentage change in payments from FY 2011 to FY 2012. The proposed change represented in Column 4 includes the proposed 1.5 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, proposed capital payments per case in FY 2012 are expected to increase as compared to capital payments per case in FY 2011. The proposed capital rate for FY 2012 would increase approximately 0.60 percent as compared to the FY 2011 capital rate. The proposed changes to the GAFs are expected to result, on average, in a slight decrease in capital payments for most regions with the following exceptions. We estimate that the GAFs will result in a slight increase in capital payments for the West North Central and West South Central urban and rural regions, as well as a slight increase for Puerto Rico and the Pacific rural region. The West North Central urban and rural regions include the frontier States that have a wage index of no less than 1.0 under the provisions of section 10324 of the Affordable Care Act, which creates the slight increase in capital IPPS payments for FY 2012. For the West South Central urban and rural regions, increases in their wage data are creating the estimated increase in their FY 2012 capital IPPS payments. The GAFs for hospitals located in Puerto Rico results in a positive effect in estimated capital IPPS payments in FY 2012 because of the application of a Puerto Rico rural floor—FY 2012 is the first year an IPPS hospital is located in rural Puerto Rico and, therefore, setting a rural floor. The most significant increase resulting from the proposed changes to the GAFs is for the New England urban region. We estimate the proposed changes to the GAFs would result in a 3.9 percent increase in capital payments per case in FY 2012 compared to FY 2011 due to the application of the rural floor in Massachusetts. Previously, there had been no IPPS hospitals in Massachusett's rural areas, but the conversion of a CAH in rural Massachusetts to an IPPS hospital has set a rural floor for that State for FY 2012.

We also are estimating a slight decrease in outlier payments from FY 2011 to FY 2012 due primarily to an estimated increase in capital IPPS payments per discharge. Because capital payments per discharge are projected to be higher in FY 2012 compared to FY 2011, fewer cases would qualify for outlier payments.

The net impact of these proposed changes, as discussed above, is an estimated 1.7 percent change in capital payments per discharge from FY 2011 to FY 2012 for all hospitals (as shown below in Table III).

The geographic comparison shows that, on average, all hospitals, urban and rural, are expected to experience an increase in capital IPPS payments per case in FY 2012 as compared to FY 2011. Capital IPPS payments per case for urban hospitals are estimated to increase 1.7 percent, while rural hospitals are expected to experience a 1.4 percent increase.

The change comparisons by region shows that most urban regions would experience, on average, increases in capital IPPS payments of between 1.0 percent for the East North Central urban region, and 5.4 percent for the New England urban region. As discussed above, the New England urban region is estimated to have a larger than average increase in capital payments per case in FY 2012 as compared to FY 2011 due to the application of a rural floor. The rural regions show estimates of a 0.8 percent change in capital payments from FY 2011 to FY 2012 in the East North Central rural region to a 3.0 percent increase for the Puerto Rico rural region. This estimated increase in capital IPPS payments for the Puerto Rico rural region is due to the application of a rural floor, as discussed above.

By type of ownership, government hospitals are estimated to experience a 1.6 percent increase in capital payments per case; voluntary hospitals, an estimated 1.7 percent increase in capital payments; and proprietary hospitals, an estimated 1.8 percent increase in capital payments from FY 2011 to FY 2012.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2012. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index.

To present the effects of the hospitals being reclassified for FY 2012, we show the average capital payments per case for reclassified hospitals for FY 2011. All reclassified and non-reclassified hospitals are expected to experience an increase in capital payments in FY 2012 as compared to FY 2011. Urban reclassified hospitals are estimated to experience the largest increase of 1.9 percent, while urban nonreclassified and rural reclassified are both estimated to have a 1.6 percent increase. For rural nonreclassified hospitals, the estimated increase in capital payments per case is 1.2 percent. Other reclassified hospitals (that is, hospitals reclassified under section 1886(d)(8)(B) of the Act) are expected to experience an increase of 0.7 percent in capital payments from FY 2011 to FY 2012.

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TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2011 PAYMENTS COMPARED TO PROPOSED FY 2012 PAYMENTS]

	Number of hospitals	Average FY 2011 payments/ case	Proposed Average FY 2012 payments/ case	Change
By Geographic Location:				
All hospitals	3,419	787	800	1.7
Large urban areas (populations over 1 million)	1,369	866	881	1.7
Other urban areas (populations of 1 million of fewer)	1,123	775	787	1.6
Rural areas	927	542	550	1.4
Urban hospitals	2,492	825	839	1.7
0-99 beds	634	666	678	1.7
100-199 beds	777	711	723	1.7
200-299 beds	457	769	781	1.7
300-499 beds	428	842	854	1.4
500 or more beds	196	1,001	1,021	2.0
Rural hospitals	927	542	550	1.4
0-49 beds	317	431	439	1.8
50-99 beds	351	499	506	1.4
100-149 beds	153	546	554	1.5
150-199 beds	60	598	606	1.4
200 or more beds	46	658	667	1.3
By Region:				
Urban by Region	2,492	825	839	1.7
New England	120	863	910	5.4
Middle Atlantic	320	879	889	1.1
South Atlantic	379	770	781	1.3
East North Central	401	801	809	1.0
East South Central	153	730	738	1.1
West North Central	168	816	832	1.9
West South Central	365	780	797	2.2
Mountain	159	848	863	1.7
Pacific	377	983	1,000	1.8
Puerto Rico	50	378	389	2.9
Rural by Region	927	542	550	1.4
New England	23	721	728	0.9
Middle Atlantic	69	554	563	1.5
South Atlantic	165	529	537	1.6
East North Central	120	574	579	0.8
East South Central	171	498	503	1.1
West North Central	99	570	582	2.0
West South Central	184	483	493	2.0
Mountain	66	575	582	1.3
Pacific	29	685	700	2.2
Puerto Rico	1	163	168	3.0
By Payment Classification:				
All hospitals	3,419	787	800	1.7
Large urban areas (populations over 1 million)	1,382	865	880	1.7
Other urban areas (populations of 1 million of fewer)	1,132	775	788	1.6
Rural areas	905	544	551	1.4
Teaching Status:				
Non-teaching	2,389	671	682	1.7
Fewer than 100 Residents	790	786	797	1.5
100 or more Residents	240	1,113	1,135	1.9
Urban DSH:				
100 or more beds	1,543	849	864	1.8
Less than 100 beds	339	591	601	1.6
Rural DSH:				
Sole Community (SCH/EACH)	416	475	483	1.7

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2011 PAYMENTS COMPARED TO PROPOSED FY 2012 PAYMENTS]

	Number of hospitals	Average FY 2011 payments/ case	Proposed Average FY 2012 payments/ case	Change
Referral Center (RRC/EACH)	222	596	605	1.5
Other Rural:				
100 or more beds	28	480	483	0.7
Less than 100 beds	133	452	458	1.3
Urban teaching and DSH:				
Both teaching and DSH	825	919	935	1.7
Teaching and no DSH	144	807	816	1.1
No teaching and DSH	1,057	711	724	1.9
No teaching and no DSH	488	734	744	1.3
Rural Hospital Types:				
Non special status hospitals	2,396	829	843	1.7
RRC/EACH	56	741	749	1.0
SCH/EACH	33	725	740	2.0
Medicare-dependent hospitals (MDH)	12	557	569	2.0
SCH, RRC and EACH	17	769	784	1.9
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2012 Reclassifications:				
All Urban Reclassified	469	836	851	1.9
All Urban Non-Reclassified	1,990	825	838	1.6
All Rural Reclassified	336	587	596	1.6
All Rural Non-Reclassified	529	474	479	1.2
Other Reclassified Hospitals (Section 1886(d)(8)(B))	55	547	551	0.7
Type of Ownership:				
Voluntary	1,991	801	814	1.7
Proprietary	850	709	721	1.8
Government	574	807	819	1.6
Medicare Utilization as a Percent of Inpatient Days:				
0-25	359	1,006	1,025	1.9
25-50	1,703	837	851	1.7
50-65	1,089	667	676	1.4
Over 65	195	580	588	1.4

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IX. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

A. Introduction and General Considerations

In section VII. of the preamble and section V. of the Addendum to this proposed rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2012. In the preamble, we specify the statutory authority for the proposed provisions that are presented, identify those proposed policies, and present rationales for our proposed decisions as well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the proposed changes to the payment rates, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

Currently, our database of 422 LTCHs includes the data for 82 nonprofit (voluntary ownership control) LTCHs and 322 proprietary LTCHs. Of the remaining 18 LTCHs, 12 LTCHs are government-owned and operated and the ownership type of the other 6 LTCHs is unknown. In the impact analysis, we used the proposed rates, factors, and policies presented in this proposed rule, including the proposed 1.5 percent annual update, which is based on the full increase of the proposed LTCH PPS market basket and the reductions required by sections 1886(m)(3) and (m)(4) of the Act, the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, including the proposed application of a budget neutrality adjustment for changes to the area wage adjustment, and the best available claims and CCR data to estimate the change in payments for FY 2012. The proposed standard Federal rate for FY 2012 is $40,082.61. This proposed rate reflects the proposed 1.5 percent annual update to the standard Federal rate and the proposed area wage level budget neutrality factor of 0.99723, which ensures that the proposed changes in the wage indexes and labor-related share do not influence estimated aggregate payments.

Based on the best available data for the 422 LTCHs in our database, we estimate that the proposed update to the standard Federal rate for FY 2012 (discussed in section V.A.2. of the Addendum to this proposed rule) and the proposed changes to the area wage adjustment for FY 2012 (discussed in section V.B. of the Addendum to this proposed rule), in addition to an estimated increase in HCO payments and an estimated increase in SSO payments, would result in an increase in estimated payments from FY 2011 of approximately $95.0 million (or about 1.9 percent). Based on the 422 LTCHs in our database, we estimate FY 2012 LTCH PPS payments to be approximately $5.233 billion, an increase from FY 2011 LTCH PPS payments which were approximately $5.138 billion. Because the combined distributional effects and estimated changes to the Medicare program payments are approximately $100 million, this proposed rule is considered a major economic rule, as defined in this section. We note the approximately $95 million for the projected increase in estimated aggregate proposed LTCH PPS payments from FY 2011 to FY 2012 does not reflect changes in LTCH admissions or case-mix intensity in estimated LTCH PPS payments, which also would affect overall payment changes.

The projected 1.9 percent increase in estimated proposed payments per discharge from FY 2011 to FY 2012 is attributable to several factors, including the proposed 1.5 percent annual update to the standard Federal rate, and projected increases in proposed estimated HCO and SSO payments. As Table IV shows, the change attributable

solely to the proposed update to the standard Federal rate is projected to result in an increase of 1.3 percent in estimated payments per discharge from FY 2011 to FY 2012, on average, for all LTCHs. Because we are proposing to apply an area wage level budget neutrality factor to the standard Federal rate, the proposed update to the wage data and labor-related share does not impact the proposed increase in payments.

As discussed in section V.B. of the Addendum to this proposed rule, we are proposing to update the wage index values for FY 2012 based on the most recent available data. In addition, we are proposing a decrease in the labor-related share from 75.271 percent to 70.334 percent under the LTCH PPS for FY 2012, based on the most recent available data on the relative importance of the proposed labor-related share of operating and capital costs of the proposed FY 2008-based RPL market basket. We also are proposing to apply an area wage level budget neutrality factor to the standard Federal rate to ensure that annual changes to the area wage level adjustment (that is, the wage index and labor-related changes) are budget neutral. We are proposing an area wage level budget neutrality factor of 0.99723, which reduces the proposed standard Federal rate by 0.28 percent. Therefore, the proposed changes to the wage data and labor-related share do not result in a change in aggregate LTCH PPS payments.

Table IV below shows the impact of the proposed payment rate and proposed policy changes on LTCH PPS payments for FY 2012 presented in this proposed rule by comparing estimated FY 2011 payments to estimated FY 2012 payments. The projected increase in payments per discharge from FY 2011 to FY 2012 is 1.9 percent (shown in Column 8). This projected increase in payments is attributable to the impacts of the proposed change to the standard Federal rate (1.3 percent in Column 6), as well as the effect of the estimated increase in payments for HCO cases and SSO cases in FY 2012 as compared to FY 2011 (0.2 percent and 0.3 percent, respectively). That is, estimated total HCO payments are projected to increase from FY 2011 to FY 2012 in order to ensure that estimated HCO payments would be 8 percent of the total estimated LTCH PPS payments in FY 2012. An analysis of the most recent available LTCH PPS claims data (that is, FY 2010 claims data from the December 2010 update of the MedPAR file) indicates that the FY 2011 HCO threshold of $18,785 (as established in the FY 2011 IPPS/LTCH PPS final rule) may result in HCO payments in FY 2011 that fall slightly below the estimated 8 percent. Specifically, we currently estimate that HCO payments would be approximately 7.8 percent of the estimated total LTCH PPS payments in FY 2011. We estimate that the impact of the increase in HCO payments would result in approximately a 0.2 percent increase in estimated payments from FY 2011 to FY 2012, on average, for all LTCHs. Furthermore, in calculating the estimated increase in payments from FY 2011 to FY 2012 for HCO and SSO cases, we increased estimated costs by the applicable market basket percentage increase as projected by our actuaries, which increases estimated payments by 0.3 percent relative to last year. We note that estimated payments for all SSO cases comprise approximately 13 percent of the estimated total LTCH PPS payments, and estimated payments for HCO cases comprise approximately 8 percent of the estimated total LTCH PPS payments. Payments for HCO cases are based on 80 percent of the estimated cost of the case above the HCO threshold, while the majority of the payments for SSO cases (over 65 percent) are based on the estimated cost of the SSO case.

As we discuss in detail throughout this proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS would result in an increase in estimated aggregate LTCH PPS payments and that the resulting LTCH PPS payment amounts would result in appropriate Medicare payments.

B. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 2.8 percent increase in estimated payments per discharge for FY 2012 as compared to FY 2011 for rural LTCHs that would result from the proposed changes presented in this proposed rule, as well as the effect of estimated changes to HCO and SSO payments. This estimated impact is based on the data for the 26 rural LTCHs in our database (out of 422 LTCHs) for which complete data were available.

The estimated increase in LTCH PPS payments from FY 2011 to FY 2012 for rural LTCHs is primarily due to the higher than average impacts from the proposed changes to the area wage level adjustment, specifically, the proposed reduction to the labor-related share from 75.271 to 70.334. Although we are proposing to apply an area wage level budget neutrality factor for proposed changes to the wage indexes and labor-related share to ensure that there is no change in aggregate LTCH PPS payments due to those changes, we estimate rural hospitals would experience a 0.8 percent increase in payments due to the proposed changes to the area wage level adjustment, as shown in Column 7 below. Rural hospitals generally have a wage index of less than 1; therefore, a proposed decrease to the labor-related share results in their proposed wage index reducing a smaller portion of the standard Federal rate, resulting in an estimated increase in payments in FY 2012 as compared to FY 2011.

C. Anticipated Effects of Proposed LTCH PPS Payment Rate Change and Policy Changes

1. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs "maintain budget neutrality." We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

As discussed above in section IX.A. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2012 of approximately $95 million (or 1.9 percent) based on the 422 LTCHs in our database.

2. Anticipated Effects of Proposed Requirements for LTCH Quality Reporting Program

In section VII.C. of the preamble of this proposed rule, we discuss our proposed requirements for LTCHs to report quality data under the LTCH quality reporting program. As set forth at section 1886(m)(5)(A) of the Act, beginning with FY 2014, the Secretary must reduce by 2.0 percentage points any annual update to the standard Federal rate for discharges for any LTCH which does not comply with the LTCH quality data submission requirements. When the policy is implemented for FY 2014, we estimate that few LTCHs would not receive the full payment update in any fiscal year. We believe that most of these LTCHs would be either small rural or small urban LTCHs. However, at this time, information is not available to determine the precise number of LTCHs that will not meet the requirements for the full hospital market basket increase for FY 2014.

In section VII.C. of the preamble of this proposed rule, we are proposing three quality reporting measure for LTCHs for FY 2014: (1) Catheter-Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Blood Stream Infection Event (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened. We estimate that the total LTCH costs to report these data, including: NHSN registration and training for the CAUTI and CLABSI quality measures; data submission for all three measures, and monitoring data submission to be $1,128,440.

3. Impact of Proposed Application of LTCH Moratorium on the Increase in Beds at Section 114(d)(1)(B) of Public Law 110–173 (MMSEA) to LTCHs and LTCH Satellite Facilities Established or Classified as Such Under Section 114(d)(1)(B) of Public Law 110–173

As discussed in section VII.F. of the preamble of this proposed rule, at proposed § 412.23(e)(8), for the period beginning October 1, 2011, and ending December 28, 2012, we are proposing to apply the moratorium on the increase in the number of beds under section 114(d)(1)(B) of the MMSEA, and specified in paragraph (e)(7) to LTCHs and LTCH satellite facilities that were established or classified as such after the December 29, 2007 under one of the exceptions to the moratorium at section 114(d)(2) of the MMSEA, as set forth in paragraph (e)(6)(ii). The proposed regulation precludes an LTCH or LTCH satellite that was developed under an exception to the establishment of new LTCHs and LTCH satellites from increasing the number of Medicare-certified beds beyond the initial number for which the facility was first paid under the LTCH PPS. Approximately 50 LTCHs and 8 satellite facilities were developed under the exceptions at § 412.23(e)(6)(ii). Because additional

increases in the number of LTCH beds in these facilities could result in added costs to the Medicare program, the impact of precluding additional growth in the number of Medicare certified beds in these facilities is expected to result in no additional spending under the Medicare program from these LTCHs and LTCH satellites.

4. Impact of the Proposed Clarification to the Greater than 25 Day Average Length of Stay Requirement for LTCHs

In section VII.E.5. of the preamble of this proposed rule, we have proposed two clarifications to our existing policy for determining whether a hospital is meeting the greater than 25 day average length of stay requirement for payment under the LTCH PPS. First, we are proposing to clarify and revise the regulations at § 412.23(e)(3)(iv) dealing with the average length of stay determination when there is a change of ownership of either a hospital seeking to qualify as an LTCH or of an existing LTCH. Second, we describe, and are proposing to clarify, our existing policy regarding the inclusion of Medicare Advantage days in the average length of stay calculation. Because typically LTCHs track the lengths of stay of their Medicare patients on an on-going basis for purposes of maintaining their LTCH status and Medicare contractors are already tasked with evaluating each LTCH's average length of stay, we do not believe that there is any actual impact resulting from the clarification of these existing policies nor do they impose any additional burdens on either LTCHs or Medicare contractors.

5. Impact on Providers

The basic methodology for determining a per discharge LTCH PPS payment is set forth in § 412.515 through § 412.536. In addition to the basic MS–LTC–DRG payment (the standard Federal rate multiplied by the MS–LTC–DRG relative weight), we make adjustments for differences in area wage levels, the COLA for Alaska and Hawaii, and SSOs. Furthermore, LTCHs may also receive HCO payments for those cases that qualify based on the threshold established each year.

To understand the impact of the proposed changes to the LTCH PPS payments presented in this proposed rule on different categories of LTCHs for FY 2012, it is necessary to estimate payments per discharge for FY 2011 using the rates, factors (including the FY 2011 GROUPER (Version 28.0)), and relative weights and the policies established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50364 through 50400 and 50442 through 50449). It is also necessary to estimate the payments per discharge that would be made under the proposed LTCH PPS rates, factors, policies, and GROUPER (proposed Version 29.0) for FY 2012 (as discussed in VII. of the preamble and section V. of the Addendum to this proposed rule). These estimates of FY 2011 and FY 2012 LTCH PPS payments are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for SSO and HCO cases in each year. We also evaluated the proposed change in estimated FY 2011 payments to estimated FY 2012 payments (on a per discharge basis) for each category of LTCHs.

Hospital groups were based on characteristics provided in the OSCAR data, FY 2008 through FY 2009 cost report data in HCRIS, and PSF data. Hospitals with incomplete characteristics were grouped into the "unknown" category. Hospital groups include the following:

- Location: Large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

To estimate the impacts of the proposed payment rates and policy changes among the various categories of existing providers, we used LTCH cases from the FY 2010 MedPAR file to estimate payments for FY 2011 and to estimate payments for FY 2012 for 422 LTCHs. We believe that the discharges based on the FY 2010 MedPAR data for the 422 LTCHs in our database, which includes 322 proprietary LTCHs, provide sufficient representation in the MS–LTC–DRGs containing discharges for patients who received LTCH care for the most commonly treated LTCH patients' diagnoses.

6. Calculation of Prospective Payments

For purposes of this impact analysis, to estimate per discharge payments under the LTCH PPS, we simulated payments on a case-by-case basis using LTCH claims from the FY 2010 MedPAR files. For modeling estimated LTCH PPS payments for FY 2011, we applied the FY 2011 standard Federal rate (that is, $39,599.95, under which LTCH discharges occurring on or after October 1, 2010, to September 30, 2011 are paid). For modeling estimated LTCH PPS payments for FY 2012, we applied the proposed FY 2012 standard Federal rate of $40,082.61, which would be effective for LTCH discharges occurring on or after October 1, 2011, and through September 30, 2012. The proposed FY 2012 standard Federal rate of $40,082.61 includes the proposed application of an area wage level budget neutrality factor of 0.99723 (as discussed in section VII.E.4. of the preamble of this proposed rule).

Furthermore, in modeling estimated LTCH PPS payments for both FY 2011 and FY 2012 in this impact analysis, we applied the FY 2011 and the proposed FY 2012 adjustments for area wage levels and the proposed COLA for Alaska and Hawaii. Specifically, we adjusted for differences in area wage levels in determining estimated FY 2011 payments using the current LTCH PPS labor-related share of 75.271 percent (75 FR 50445) and the wage index values established in the Tables 12A and 12B of the Addendum to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50627 through 50646). We also applied the FY 2011 COLA factors shown in the table in section V.B.5. of the Addendum to that final rule (75 FR 50446) to the FY 2011 nonlabor-related share (24.729 percent) for LTCHs located in Alaska and Hawaii. Similarly, we adjusted for differences in area wage levels in determining estimated FY 2012 payments using the proposed LTCH PPS FY 2012 labor-related share of 70.334 percent and the proposed FY 2012 wage index values presented in Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (and available via the Internet). We also applied the proposed FY 2012 COLA factors shown in the table in section V.B.5. of the Addendum to the FY 2011 IPPS/LTCH PPS final rule to the proposed FY 2012 nonlabor-related share (29.666 percent) for LTCHs located in Alaska and Hawaii.

As discussed above, our impact analysis reflects an estimated change in payments for SSO cases, as well as an estimated increase in payments for HCO cases (as described in section V.C. of the Addendum to this proposed rule). In modeling proposed payments for SSO and HCO cases in FY 2012, we applied an inflation factor of 1.055 (determined by OACT) to the estimated costs of each case determined from the charges reported on the claims in the FY 2010 MedPAR files and the best available CCRs from the December 2010 update of the PSF. Furthermore, in modeling estimated LTCH PPS payments for FY 2012 in this impact analysis, we used the proposed FY 2012 fixed-loss amount of $19,270 (as discussed in section V.C. of the Addendum to this proposed rule).

These impacts reflect the estimated "losses" or "gains" among the various classifications of LTCHs from the FY 2011 to FY 2012 based on the proposed payment rates and policy changes presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the LTCH PPS among various classifications of LTCHs.

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases.
- The fourth column shows the estimated payment per discharge for FY 2011 (as described above).
- The fifth column shows the estimated payment per discharge for FY 2012 (as described above).
- The sixth column shows the percentage change in estimated payments per discharge from FY 2011 to FY 2012 due to the proposed update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge from FY 2011 to FY 2012 for proposed changes to the area wage level adjustment (that is, the proposed wage indexes and proposed labor-related share) including the proposed application of an area wage level budget neutrality factor (as discussed in section V.B.5. of the Addendum to the proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge from FY 2011 (Column 4) to FY 2012 (Column 5) for all proposed changes (and includes the effect of estimated proposed changes to HCO and SSO payments).

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TABLE IV: IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR FY 2012 (ESTIMATED FY 2011 PAYMENTS COMPARED TO ESTIMATED PROPOSED FY 2012 PAYMENTS*)

LTCH Classification (1)	Number of LTCHs (2)	Number of LTCH PPS Cases (3)	Average FY 2011 LTCH PPS Payment Per Case[1] (4)	Average FY 2012 LTCH PPS Proposed Payment Per Case[2] (5)	Percent Change in Estimated Payments Per Discharge from FY 2011 to FY 2012 for the Proposed Annual Update to the Federal Rate[2] (6)	Percent Change in Estimated Payments Per Discharge from FY 2011 to FY 2012 for Proposed Changes to the Area Wage Level Adjustment with Proposed Budget Neutrality[3] (7)	Percent Change in Payments Per Discharge from FY 2011 to FY 2012 for All Proposed Changes[4] (8)
ALL PROVIDERS	422	134,805	$38,115	$38,820	1.3	0.0	1.9
BY LOCATION:							
RURAL	26	5,854	$33,611	$34,550	1.4	0.8	2.8
URBAN	396	128,951	$38,320	$39,014	1.3	0.0	1.8
LARGE	204	77,381	$40,098	$40,745	1.3	-0.2	1.6
OTHER	192	51,570	$35,651	$36,416	1.4	0.3	2.2
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	16	5,884	$33,874	$34,280	1.3	-0.6	1.2
OCT. 1983 - SEPT. 1993	44	16,648	$40,063	$40,762	1.3	-0.3	1.7
OCT. 1993 - SEPT. 2002	186	63,258	$37,248	$37,938	1.3	0.1	1.9
AFTER OCTOBER 2002	173	48,210	$39,117	$39,870	1.4	0.1	1.9
UNKNOWN PARTICIPATION DATE	3	805	$36,962	$38,300	1.4	1.7	3.6
BY OWNERSHIP TYPE:							
VOLUNTARY	82	19,507	$39,280	$40,097	1.3	-0.1	2.1
PROPRIETARY	322	113,029	$37,836	$38,521	1.3	0.0	1.8
GOVERNMENT	12	1,693	$43,296	$44,059	1.3	-0.5	1.8
UNKNOWN OWNERSHIP TYPE	6	576	$38,191	$38,970	1.3	0.0	2.0
BY REGION:							
NEW ENGLAND	15	7,283	$33,832	$34,156	1.3	-0.7	1.0
MIDDLE ATLANTIC	30	7,957	$39,016	$39,739	1.3	0.0	1.9
SOUTH ATLANTIC	57	15,487	$41,372	$42,106	1.3	-0.2	1.8
EAST NORTH CENTRAL	68	19,780	$39,942	$40,516	1.3	-0.4	1.4

LTCH Classification (1)	Number of LTCHs (2)	Number of LTCH PPS Cases (3)	Average FY 2011 LTCH PPS Payment Per Case[1] (4)	Average FY 2012 LTCH PPS Proposed Payment Per Case[2] (5)	Percent Change in Estimated Payments Per Discharge from FY 2011 to FY 2012 for the Proposed Annual Update to the Federal Rate[2] (6)	Percent Change in Estimated Payments Per Discharge from FY 2011 to FY 2012 for Proposed Changes to the Area Wage Level Adjustment with Proposed Budget Neutrality[3] (7)	Percent Change in Payments Per Discharge from FY 2011 to FY 2012 for All Proposed Changes[4] (8)
EAST SOUTH CENTRAL	29	8,158	$37,727	$38,521	1.3	0.2	2.1
WEST NORTH CENTRAL	26	5,899	$39,847	$40,743	1.3	0.3	2.3
WEST SOUTH CENTRAL	141	50,707	$33,617	$34,412	1.4	0.5	2.4
MOUNTAIN	32	6,724	$41,617	$42,293	1.3	-0.3	1.6
PACIFIC	24	12,810	$48,649	$49,242	1.3	-0.6	1.2
BY BED SIZE:							
BEDS: 0-24	29	3,728	$32,665	$33,483	1.4	0.5	2.5
BEDS: 25-49	196	43,731	$37,536	$38,247	1.4	0.1	1.9
BEDS: 50-74	112	35,963	$38,762	$39,518	1.4	0.1	2.0
BEDS: 75-124	49	22,005	$40,891	$41,555	1.3	-0.3	1.6
BEDS: 125-199	21	14,824	$36,329	$36,961	1.3	0.0	1.7
BEDS: 200 +	15	14,554	$37,275	$37,942	1.3	0.1	1.8

[1] Estimated FY 2012 LTCH PPS payments based on the proposed payment rates and policy changes presented in the preamble and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge from FY 2011 to FY 2012 for the proposed annual update to the standard Federal rate, as discussed in section V.A.2. of the Addendum to this proposed rule.

[3] Percent change in estimated payments per discharge from FY 2011 to FY 2012 for proposed changes to the area wage level adjustment at §412.525(c) (as discussed in section V.B. of the Addendum to this proposed rule).

[4] Percent change in estimated payments per discharge from FY 2011 LTCH PPS (shown in Column 4) to FY 2012 LTCH PPS (shown in Column 5), including all of the proposed changes presented in the preamble and the Addendum to this proposed rule. Note, this column, which shows the percent change in estimated payments per discharge for all proposed changes, does not equal the sum of the percent changes in estimated payments per discharge for the proposed annual update to the standard Federal rate (column 5) and the proposed changes to the area wage level adjustment with budget neutrality (Column 6) due to the effect of estimated changes in both estimated payments to SSO cases that are paid based on estimated costs and aggregate HCO payments (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

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7. Results

Based on the most recent available data for 422 LTCHs, we have prepared the following summary of the impact (as shown above in Table IV) of the proposed LTCH PPS payment rate and policy changes presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge are expected to increase approximately 1.9 percent, on average, for all LTCHs from FY 2011 to FY 2012 as a result of the proposed payment rate and policy changes presented in this proposed rule, as well as estimated increases in HCO and SSO payments. We note that we applied a proposed 1.5 percent annual update in determining the proposed standard Federal rate for FY 2012, based on the latest estimate of the proposed LTCH PPS market basket increase (2.8 percent), the proposed reduction of 1.2 percentage points for the multifactor productivity adjustment and the 0.1 percentage point reduction required under sections 1886(m)(3) and (m)(4) of the Act. We noted earlier in this section that for most categories of LTCHs, as shown in Table IV (Column 6), the impact of the increase of approximately 1.5 percent for the proposed annual update to the standard Federal rate is projected to result in approximately a 1.3 percent change in estimated payments per discharge for all LTCHs from FY 2011 to FY 2012. Because payments to cost-based SSO cases and a portion of payments to SSO cases that are paid based on the "blend" option of the SSO payment formula at § 412.529(c)(2)(iv) are not affected by the proposed annual update to the standard Federal rate, we estimate that the effect of the proposed 1.5 percent annual update to the standard Federal rate would result in a 1.3 percent increase on estimated aggregate LTCH PPS payments to *all* LTCH PPS cases, including SSO cases. Furthermore, as discussed previously in this regulatory impact analysis, the average increase in estimated payments per discharge from the FY 2011 to FY 2012 for all LTCHs of approximately 1.9 percent (as shown in Table IV) was determined by comparing estimated FY 2012 LTCH PPS payments (using the proposed rates and policies discussed in this proposed rule) to estimated FY 2011 LTCH PPS payments (as described above in section IX.C.5. of this Appendix).

a. Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 6 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH cases are treated in these rural hospitals. The impact analysis presented in Table IV shows that the average percent increase in estimated payments per discharge from FY 2011 to FY 2012 for all hospitals is 1.9 percent for all proposed changes. For rural LTCHs, the percent change for all proposed changes is estimated to be 2.8 percent, while for urban LTCHs, we estimate the increase to be 1.8 percent. Large urban LTCHs are projected to experience an increase of 1.6 percent in estimated payments per discharge from FY 2011 to FY 2012, while other urban LTCHs are projected to experience an increase of 2.2 percent in estimated payments per discharge from FY 2011 to FY 2012, as shown in Table IV.

b. Participation Date

LTCHs are grouped by participation date into four categories: (1) before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) after October 2002. Based on the most recent available data, the majority (approximately 47 percent) of the LTCH cases are in hospitals that began participating in the Medicare program between October 1993 and September 2002, and are projected to experience nearly the average increase (1.9 percent) in estimated payments per discharge from FY 2011 to FY 2012, as shown in Table IV.

In the participation category where LTCHs began participating in the Medicare program before October 1983, LTCHs are projected to experience a lower than average percent increase (1.2 percent) in estimated payments per discharge from FY 2011 to FY 2012, as shown in Table IV. Approximately 4 percent of LTCHs began participating in Medicare before October 1983. The LTCHs in this category are projected to experience a lower than average increase in estimated payments because of decreases in payments due to the proposed changes to the area wage adjustment. Approximately 10 percent of LTCHs began participating in Medicare between October 1983 and September 1993. These LTCHs are also projected to experience a slightly lower than average increase (1.7 percent) in estimated payments from FY 2011 to FY 2012. LTCHs that began participating in Medicare after October 2002 currently represent approximately 41 percent of all LTCHs, and are projected to experience an average increase (1.9 percent) in estimated payments from FY 2011 to FY 2012.

c. Ownership Control

Other than LTCHs whose ownership control type is unknown, LTCHs are grouped into three categories based on ownership control type: voluntary, proprietary, and government. Based on the most recent available data, approximately 19 percent of LTCHs are identified as voluntary (Table IV). We expect that, for these LTCHs in the voluntary category, estimated FY 2012 LTCH payments per discharge would increase higher than the average (2.1 percent) in comparison to estimated payments in FY 2011 primarily because we project an increase in estimated HCO payments and SSO payments to be higher than the average for these LTCHs. The majority (76 percent) of LTCHs are identified as proprietary and these LTCHs are projected to experience a nearly average increase (1.8 percent) in estimated payments per discharge from FY 2011 to FY 2012. Finally, government-owned and operated LTCHs (3 percent) are also expected to experience a nearly average increase in payments of 1.8 percent in estimated payments per discharge from FY 2011 to FY 2012.

d. Census Region

Estimated payments per discharge for FY 2012 are projected to increase for LTCHs located in all regions in comparison to FY 2011. Of the 9 census regions, we project that the increase in estimated payments per discharge would have the largest positive impact on LTCHs in the West South Central region (2.4 percent, as shown in Table IV). The estimated percent increase in payments per discharge from FY 2011 to FY 2012 for the West South Central is largely attributable to the proposed changes in the area wage level adjustment.

In contrast, LTCHs located in the New England region are projected to experience the smallest increase in estimated payments per discharge from FY 2011 to FY 2012. The average estimated increase in payments of 1.0 percent for LTCHs in the New England region is primarily due to estimated decreases in payments associated with the area wage level adjustment.

e. Bed Size

LTCHs were grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds.

We project that payments for small LTCHs (0–24 beds) would experience a 2.5 percent increase in payments due to increases in the proposed area wage adjustment while large LTCHs (200+ beds) would experience a 1.8 percent increase in payments. LTCHs with between 75 and 124 beds and between 125 and 199 beds are expected to experience a slightly below average increase in payments per discharge from FY 2011 to FY 2012 (1.6 percent and 1.7 percent, respectively) primarily due to an estimated decreases in their payments from FY 2011 to FY 2012 due to the proposed area wage level adjustment.

D. Effect on the Medicare Program

As noted previously, we project that the provisions of this proposed rule would result in an increase in estimated aggregate LTCH PPS payments in FY 2012 of approximately $95.0 million (or about 1.9 percent) for the 422 LTCHs in our database.

E. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries under the LTCH PPS, but we continue to expect that paying prospectively for LTCH services would enhance the efficiency of the Medicare program.

X. Alternatives Considered

A. General

This proposed rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

B. Alternative Considered for Hospital Inpatient Quality Review (IQR) and Value-Based Purchasing (VBP) Programs: Medicare Spending per Beneficiary Measure

In section IV.A.3.b.(ii)(B) of the preamble to this proposed rule, we are proposing to adopt a claims-based Medicare spending per beneficiary measure for the FY 2014 Hospital IQR Program. In section IV.B.3.b.(iii) of the preamble of this proposed rule, we are proposing to adopt this claims-based Medicare spending per beneficiary measure for the FY 2014 Hospital VBP Program. For the Medicare spending per beneficiary measure, we considered an alternative approach based on the principle that Medicare spending per beneficiary benchmarks for lower quality hospitals should not exceed the benchmarks for higher quality hospitals. This alternative approach is more complex than our proposal. Due to its increased complexity, we are including the discussion of this alternative approach here rather than earlier in the preamble for ease of presentation: both the efficiency measure and its scoring as part of the Hospital VBP Program can be presented in a continuous narrative.

As noted earlier, the NQF has not endorsed a Medicare spending per beneficiary measure. However, its 2009 report "Measurement Framework: Evaluating Efficiency Across Patient-Focused Episodes of Care" (NQF 2009), discusses four general terms that are helpful in framing the discussion of an alternative Medicare Spending per Beneficiary measure.

- Quality of care is a measure of performance on the Institute of Medicine's (IOM) six aims for healthcare: safety, timeliness, effectiveness, efficiency, equity, and patient centeredness.
- Cost of care is a measure of the total healthcare spending, including total resource use and unit price(s), by payor or consumer, for a healthcare service or group of healthcare services associated with a specified patient population, time period, and unit(s) of clinical accountability.
- Efficiency of care is a measure of cost of care associated with a specified level of quality of care. "Efficiency of care" is a measure of the relationship of the cost of care associated with a specific level of performance measured with respect to the other five IOM aims of quality.
- Value of care is a measure of a specified stakeholder's (such as an individual patient's, consumer organization's, payor's, provider's, government's, or society's) preference-weighted assessment of a particular combination of quality and cost of care performance." (p. 6, Measurement Framework: Evaluating Efficiency Across Patient-Focused Episodes of Care, NQF 2009)

We will examine each of these four terms (Quality of Care, Cost of Care, Efficiency of

Care, and Value of Care) in the context of an alternative to our proposed Medicare Spending per Beneficiary measure.

1. Quality of Care

As discussed in the Hospital VBP Program proposed rule, a hospital's performance on the quality measures (based on the higher of achievement or improvement) is consolidated into a single Total Performance Score for that hospital. For purposes of this discussion, we will refer to the Total Performance Score discussed in the Hospital VBP Program proposed rule as the "total quality score (TQS)."

2. Cost of Care

For purposes of this discussion, we are considering the cost of care to be the Medicare spending per beneficiary amount described in section IV.B.3.b.(3) of the preamble of this proposed rule.

3. Efficiency of Care

The term "efficiency of care" is discussed in the NQF report as a measure of cost of care associated with a specified level of quality of care. "Efficiency of care" is a measure of the relationship of the cost of care associated with a specific level of performance measured with respect to the other five IOM aims of quality. We considered the following approach to measuring the relationship between the cost of care (that is, Medicare spending per beneficiary amount) and quality of care (that is, the TQS). The result of this measurement is an efficiency score for each hospital.

Steps in Measuring the Efficiency of Care Under the Alternative Approach

Step 1:—Hospitals are grouped by total quality score (TQS).

Step 1a.—Define the first (highest) Quality Group.

The first Quality Group consists of hospitals with a TQS in the top decile of the TQSs.

$\{Quality_1\} = \{Q_1\}$ = Quality Group 1 = Hospitals in the top decile of quality = Hospitals with a TQS of 100, 99, ...α_1

Step 1b.—Define the remaining Quality Groups.

Beginning with the first TQS not included in the first Quality Group (TQS = α_1–1), add hospitals with this TQS to the hospitals in the first Quality Group. This group of hospitals forms the second Quality Group:

$\{Quality_2\} = \{Q_2\}$ = Quality Group 2 = Hospitals with a TQS ≥ (α_1–1)

Note that $\{Q_1\} \subset \{Q_2\}$, meaning $\{Q_1\}$ is a subset of $\{Q_2\}$.

The process repeats for the next Quality Group:

$\{Quality_3\} = \{Q_3\}$ = Quality Group 3 = Hospitals with a TQS ≥ (α_1–2)

Note that $\{Q_1\} \subset \{Q_2\} \subset \{Q_3\}$, meaning $\{Q_2\}$ is a subset of $\{Q_3\}$.

It continues with successively lower quality scores until the hospitals with a TQS of 1 are added.

$\{Quality_N\} = \{Q_N\}$ = Last Quality Group N = Hospitals with a TQS ≥ 1

Note that $\{Q_1\} \subset \{Q_2\} \subset \{Q_3\}$....., $\subset \{Q_N\}$, so all Quality Groups are subsets of $\{Q_N\}$ since $\{Q_N\}$ contains all hospitals with a TQS greater than or equal to 1.

Step 2: Determine the cost benchmarks for each hospital.

Step 2a—Determine the cost benchmark for the top Quality Group.

The cost benchmark for the hospitals in the top Quality Group is the mean Medicare spending per beneficiary for the hospitals in the top Quality Group.

Step 2b.—Determine the cost benchmarks for all hospitals that are not in the top Quality Group.

The cost benchmark for each hospital with TQS of j is the lower of: (1) the 10th percentile of Medicare spending per beneficiary for all hospitals in the smallest (in terms of the number of hospitals in the group) Quality Group that contains hospitals with a TQS score of j; and (2) the benchmark for the group of hospitals of next higher quality.

$\{Q\}_{j \epsilon i}$ = Smallest Quality Group $\{Q_i\}$ that contains hospitals with TQS = j

$Cost^{10}_{j \epsilon i}$ = 10th percentile of Medicare spending per beneficiary for all hospitals in $\{Q\}_{j \epsilon i}$

Cost benchmark $_j$ = Cost benchmark for all hospitals with TQS j = min ($Cost^{10}_{j \epsilon i}$, Cost Benchmark $_{j-1}$)

Step 3: Calculate the efficiency ratio for each hospital.

Calculate the efficiency ratio for hospital k with TQS j.

The efficiency ratio for hospital k with TQS j is the ratio of the Medicare spending per beneficiary for hospital k to the cost benchmark for TQS j.

$Cost_k$ = Medicare spending per beneficiary for hospital k

Efficiency $ratio_k$ = Efficiency ratio for hospital k = $Cost_k$/Cost $Benchmark_j$

Step 4: Calculate the efficiency ratio threshold and benchmark.

Step 4a. Calculate the efficiency ratio threshold.

The efficiency ratio threshold is the point at which hospitals can begin to earn efficiency points based on achievement. It is the median efficiency ratio across all hospitals.

Efficiency ratio threshold = Median efficiency ratio across all hospitals

Step 4b. Calculate the efficiency ratio benchmark.

The efficiency ratio benchmark is the point at which hospitals earn the maximum efficiency points (10) based on achievement. It is the 10th percentile of the efficiency ratios across all hospitals.

Efficiency ratio benchmark = 10th percentile efficiency ratio across all hospitals

Step 5: Calculate the efficiency points based on achievement.

Calculate the efficiency points based on achievement for hospital k.

Achievement Efficiency Points $_k$ =

$$\left[9 * \frac{(Efficiency\ Ratio_k - Efficiency\ Ratio\ Threshold)}{(Efficiency\ Ratio\ Benchmark - Efficiency\ Ratio\ Threshold)}\right] + .05$$

Step 6: Calculate the efficiency points based on improvement.

Calculate the efficiency points based on improvement for hospital k.

The performance period has a corresponding base period, analogous to the base period for other Hospital VBP measures. In order to calculate efficiency points based on improvement, an efficiency ratio would be determined for each hospital k using only the data from the base period and following Step 1 to Step 3 above. Using this base period efficiency ratio for hospital k, the

improvement points for hospital k are calculated as:

$$\text{Improvement Efficiency Points}_k = \left[10 * \frac{(Efficiency\ Ratio_k - Efficiency\ Ratio_{k(base)})}{(Efficiency\ Ratio\ Benchmark - Efficiency\ Ratio_{k(base)})}\right] - .05$$

The efficiency score for hospital k is the higher of the achievement or improvement efficiency points.

4. Value of Care

The term "value of care" is discussed in the NQF report as a measure of a specified stakeholder's (such as an individual patient's, consumer organization's, payor's, provider's, government's, or society's) preference-weighted assessment of a particular combination of quality and cost of care performance. Under our alternative Medicare spending per beneficiary approach, we considered creating an efficiency adjustment to the TQS for a hospital using a function of the general form:

Efficiency adjustment to the total quality score = A*TQS + B*(efficiency score*10) + C, where A is the weight given to the quality score, B is the weight given to the efficiency score, and C is a constant.

We multiply the efficiency score by 10 to put it on the same scale as the TQS (0 to 100).

Depending on the parameters chosen, adopting such a function for valuing efficiency could allow the TQS for a hospital to be adjusted upwards or downwards depending on the hospital's TQS and its efficiency score. For example, suppose two hospitals both have an efficiency score of 5, but one hospital has a much higher TQS than the other. We could choose parameters that would result in a negative efficiency adjustment to the TQS for the lower quality hospital and a positive efficiency adjustment to the TQS for the higher quality hospital. Under this approach, we value the efficiency score of 5 for the higher quality hospital more than the efficiency score of 5 for the lower quality hospital, hence the positive adjustment to the TQS for the higher quality hospital and the negative adjustment to the TQS for the lower quality hospital.

Using the TQS adjusted for efficiency, meaning after we apply the efficiency adjustment the TQS, the linear exchange function approach previously proposed in the Hospital VBP Program proposed rule for the hospital VBP system would be used to determine each hospital's VBP incentive payment such that the overall hospital VBP program remains budget neutral.

XI. Overall Conclusion

A. Acute Care Hospitals

Table I of section VI. of this Appendix demonstrates the estimated distributional impact of the IPPS budget neutrality requirements for the proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows an overall proposed decrease of 0.5 percent in operating payments. We estimate that operating payments would decrease by approximately $498 million in FY 2012. For FY 2012, we are proposing to distribute $250 million to hospitals that qualify to receive additional payment under section 1109 of Pub. L. 111–152, which is an additional $100 million than what we had distributed under this provision in FY 2011. In addition, we estimate a savings of $23 million associated with the HACs policies. These estimates, added to our proposed FY 2012 operating estimate of −$498 million, would result in a decrease of $421.2 million for FY 2012. We estimate that capital payments will experience a 1.8 percent increase in payments per case, as shown in Table III of section VIII. of this Appendix. We project that there would be a $146 million increase in capital payments in FY 2012 compared to FY 2011. The proposed cumulative operating and capital payments should result in a net decrease of $275 million to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this proposed rule, constitute a regulatory impact analysis.

B. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments per discharge in FY 2012. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule, including proposed updated wage index values and relative weights, and the best available claims and CCR data to estimate the proposed change in payments under the LTCH PPS for FY 2012. Accordingly, based on the best available data for the 422 LTCHs in our database, we estimate that proposed FY 2012 LTCH PPS payments would increase approximately $95 million (or about 1.9 percent).

XII. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table V below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the proposed change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

Table V.—Accounting Statement: Classification of Estimated Expenditures under the IPPS from FY 2011 to FY 2012

Category	Transfers
Annualized Monetized Transfers	-$275 million
From Whom to Whom	Federal Government to IPPS Medicare Providers
Total	-$275 million

B. LTCHs

As discussed in section IX. of this Appendix, the impact analysis for the proposed changes under the LTCH PPS for this proposed rule projects an increase in estimated aggregate payments of approximately $95 million (or about 1.9 percent) for the 422 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table VI below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to proposed changes to the LTCH PPS. Table VI provides our best estimate of the estimated increase in Medicare payments under the LTCH PPS as a result of the proposed provisions presented in this proposed rule based on the data for the 422 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

TABLE VI.—Accounting Statement: Classification of Estimated Expenditures from the FY 2011 LTCH PPS to the FY 2012 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	Positive transfer--Estimated increase in expenditures: $95 million

XII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the Puerto Rico-specific standardized amount, the hospital-specific rates for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs, IPFs, and IRFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2012

A. Proposed FY 2012 Inpatient Hospital Update

Section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2012 as equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas (which is based on IHS Global Insight Inc.'s (IGI's) first quarter 2011 forecast of the FY 2006-based IPPS market basket), subject to a reduction of 2.0 percentage points if the hospital fails to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to an adjustment based on changes in economy-wide productivity and an additional reduction of 0.1 percentage point. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Affordable Care Act, as added by section 3401(a) of the Affordable Care Act, state that the application of the multifactor productivity adjustment and the additional FY 2012 adjustment of 0.1 percentage point may result in the applicable percentage increase being less than zero.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.K.3. of the preamble of this proposed rule, we are proposing a multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 1.2 percent.

Therefore, based on IGI's first quarter 2011 forecast of the FY 2012 market basket increase, we are proposing an applicable percentage increase to the FY 2012 operating standardized amount of 1.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 1.2 percentage points for economy-wide productivity and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance with section 1886(b)(3)(B)(vii) of the Act and our rules. For hospitals that fail to submit quality data, we are proposing an applicable percentage increase to the operating standardized amount of −0.5 percent (that is, the FY 2012 estimate of the market basket rate-of increase of 2.8 percent less 2.0 percentage points for failure to submit quality data, less an adjustment of 1.2 percentage points for economy-wide productivity, and less an additional adjustment of 0.1 percentage point).

B. Proposed Update for SCHs and MDHs for FY 2012

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2012 applicable percentage increase in the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital specific rates for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, we are proposing an applicable percentage increase to the hospital-specific rates applicable to SCHs and MDHs of 1.5 percent for hospitals that submit quality data or −0.5 percent for hospitals that fail to submit quality data.

C. Proposed FY 2012 Puerto Rico Hospital Update

Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.5 percent.

D. Proposed Update for Hospitals Excluded From the IPPS

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's and cancer hospitals. Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under § 413.40, which also uses section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Section 1886(j)(3)(C) of the Act addresses the increase factor for the Federal prospective payment rate of IRFs. Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS. In addition, section 124 of Public Law 106–113 provides the statutory authority for updating all aspects of the payment rates for IPFs.

Currently, children's hospitals, cancer hospitals, and RNHCIs are the remaining three types of hospitals still reimbursed under the reasonable cost methodology. We are proposing to provide our current estimate of the FY 2012 IPPS operating market basket percentage increase (2.8 percent) to update the target limits for children's hospitals, cancer hospitals, and RNHCIs.

For FY 2012, as discussed in section VII. of the preamble to this proposed rule, we are proposing to establish an update to the LTCH PPS standard Federal rate for FY 2012 based on the full proposed LTCH PPS market basket increase estimate (2.8 percent). The proposed annual update also includes the requirement at section 1886(m)(3)(A)(i) of the Act to reduce the annual update by the productivity adjustment described in section 1886(b)(3)(B)(xi)(ii) of the Act, which is currently estimated to be 1.2 percent. In addition, the statute at section 1886(m)(3)(A)(ii) of the Act requires that any

annual update for FY 2012 be reduced by the "other adjustment" at section 1886(m)(4)(C) of the Act, which is 0.1 percentage point. Accordingly, the proposed update factor to the standard Federal rate for FY 2012 is 1.5 percent (that is, we are proposing to apply a factor of 1.015 in determining the proposed LTCH PPS standard Federal rate for FY 2012).

Effective for cost reporting periods beginning on or after January 1, 2005, IPFs are paid under the IPF PPS. IPF PPS payments are based on a Federal per diem rate that is derived from the sum of the average routine operating, ancillary, and capital costs for each patient day of psychiatric care in an IPF, adjusted for budget neutrality. In the RY 2012 IPF PPS proposed rule (76 FR 5000 through 5001), we proposed to extend the IPF PPS RY 2012 by 3 months (a total of 15 months instead of 12 months) through September 30, 2012. Based on IGI's fourth quarter 2010 forecast, with history through the third quarter of 2010, the projected 15-month market basket update based on the proposed FY 2008-based RPL market basket for the proposed 15-month RY 2012 (July 1, 2011 through September 30, 2012) is 3.0 percent. However, if we were not proposing to extend the 2012 IPF PPS rate year by 3 months, we would have proposed a market basket update of 2.6 percent for a 12-month RY 2012. In accordance with section 1886(s)(2)(A)(ii) of the Act, which requires the application of an "other adjustment," described in section 1886(s)(3) of the Act (specifically, section 1886(s)(3)(A) for RYs 2011 and 2012), that reduces the update to the IPF PPS base rate for the rate year beginning in CY 2011, we proposed to adjust the IPF PPS update by 0.25 percentage point for RY 2012. Therefore, we proposed to apply the 15-month FY 2008-based RPL market basket increase of 3.0 percent, which is then adjusted by the "other adjustment" of 0.25 percentage point.

IRFs are paid under the IRF PPS for cost reporting periods beginning on or after January 1, 2002. For cost reporting periods beginning on or after October 1, 2002 (FY 2003), and thereafter, the Federal prospective payments to IRFs are based on 100 percent of the adjusted Federal IRF prospective payment amount, updated annually (69 FR 45721). Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act require the application of a 0.1 percentage point reduction to the market basket increase factor for FYs 2012 and 2013. In addition, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment. Increase factors for the IRF PPS will be discussed in future notice and comment rulemaking.

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update equal to one percent for FY 2012. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, we are recommending an applicable percentage increase to the standardized amount of 1.5 percent (that is, the FY 2012 estimate of the market basket rate-of-increase of 2.8 percent less an MFP adjustment of 1.2 percentage points for MFP and less 0.1 percentage point). We are recommending that the same applicable percentage increase apply to SCHs and MDHs and the Puerto Rico-specific standardized amount.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for all other types of hospitals. Consistent with our proposal for these facilities, we are recommending an update for children's hospitals, cancer hospitals, and RNHCIs of 2.8 percent.

For FY 2012, consistent with policy proposal set forth in section VII. of the preamble of this proposed rule, we are recommending an update of 1.5 percent to the LTCH PPS standard Federal rate. In addition, consistent with the proposed update specified in the FY 2012 IRF PPS proposed rule (as described above), we are recommending an update of 1.5 percent (that is, the market basket increase factor of 2.8 percent less 1.2 percentage points for economy-wide productivity and less 0.1 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act) to the IRF PPS Federal rate for FY 2012. Finally, consistent with the proposed update specified in the FY 2012 IPF PPS proposed rule (as described above), we are recommending an update of 3.0 percent reduced by 0.25 percentage point to the IPF PPS Federal rate for RY 2012 for the Federal per diem payment amount.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2011 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates equal to one percent. MedPAC expects Medicare margins to remain low in 2012. At the same time though, MedPAC's analysis finds that efficient hospitals have been able to maintain positive Medicare margins while maintaining a relatively high quality of care. MedPAC also recommended that Congress should require the Secretary to make adjustments to inpatient payment rates in future years to recover all overpayments due to documentation and coding improvements. MedPAC noted that priority should be given to preventing future overpayments.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to one percent, for FY 2012, as discussed above, sections 3401(a) and 10319(a) of the Affordable Care Act amended section 1886(b)(3)(B) of the Act. Section 1886(b)(3)(B), as amended by these sections, sets the requirements for the FY 2012 applicable percentage increase. Therefore, we have proposed an applicable percentage increase for FY 2012 of 1.5 percent, provided the hospital submits quality data, consistent with these statutory requirements.

Similar to our response last year, we agree with MedPAC that hospitals should control costs rather than have Medicare accommodate the current rate of growth. As MedPAC noted, the lack of financial pressure at certain hospitals can lead to higher costs and in turn bring down the overall Medicare margin for the industry.

With regard to MedPAC's recommendation that Congress should require the Secretary to make adjustments to inpatient payment rates in future years to recover all overpayments due to diagnosis and coding improvements, we refer the reader to section III. D. of the preamble to this proposed rule for a complete discussion on the proposed FY 2012 MS–DRG documentation and coding adjustment. In section III. D. of the preamble to this proposed rule, we are proposing a prospective adjustment of 3.15 percent and a recoupment of 2.9 percent to the FY 2012 inpatient payment rates to recover overpayments due to documentation and coding improvements. We note that any recoupments for overpayments due to documentation and coding improvements beyond the authority of section 7(b)(1)(B) of Public Law 110–90 would require additional changes to current law by Congress. Therefore, without a change to current law, our ability to recoup all overpayments due to documentation and coding improvements is limited.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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